33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	101
Committee:	Tech/Scientific

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

Allow for the illumination of milk, milk products or whey with ultraviolet light (UV) as an adjunct to thermal pasteurization in order to increase the shelf life of the product.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

The delivery of ultraviolet light at 254 nm (UV) as an adjunct to pasteurization will aid in the inactivation of spoilage microbes in milk, milk products or whey. UV light inactivation of microbes is an established technology that currently has many commercial applications including municipal water supplies and juice products. UV will provide an added measure of quality and increase the availability of products to the consumer with the goal of maintaining sensory properties until the end of shelf life. As an adjunct to pasteurization, UV's ability to inactivate bacterial spores may also play a role in food defense by inactivating biosafety level three pathogens that might be introduced with criminal intent.

C. Proposed Solution

Changes to be made on page(s): Page 28 of the (X - one of the following):

X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms

_____ 2009 Procedures _____ 2009 Constitution and Bylaws

Modify the 2009 PMO, Page 28, SECTION 7. STANDARDS FOR GRADE "A" MILK AND MILK PRODUCTS

All Grade "A" raw milk or milk products for pasteurization, ultra-pasteurization, or aseptic processing and all Grade "A" pasteurized, ultra-pasteurized or aseptically processed milk and milk products, shall be produced, processed, manufactured and pasteurized, ultra-pasteurized, or aseptically processed to conform to the following chemical, physical, bacteriological and temperature standards and the sanitation requirements of this Section. No process or manipulation other than pasteurization, ultra-pasteurization or aseptic processing; processing methods integral therewith; and appropriate refrigeration shall be applied to milk and milk products for the purpose of removing or deactivating microorganisms, provided that filtration, ~~and/or~~ bactofugation, and/or ultraviolet light processes are performed in the milk plant in which the milk or milk product is pasteurized, ultra-pasteurized or aseptically processed. Provided, that in the bulk shipment of cream, nonfat (skim) milk or reduced fat or lowfat milk, the heating of the raw milk, one time, to temperatures greater than 52°C (125°F) but less than 72°C (161°F), for separation purposes, is permitted when the resulting bulk shipment(s) of cream, nonfat (skim) milk or reduced fat or lowfat milk are labeled heat-treated. In the case of heat-treated cream, the cream may be further heated to less than 75°C (166°F) in a continuing heating process and immediately cooled to 7°C (45°F) or less when necessary for enzyme deactivation (such as lipase reduction) for a functional reason.

Name: Dr. James S. Cullor

Agency/Organization: Univ. of California – Davis, School of Veterinary Medicine, Veterinary Medicine Teaching and Research Center

Address: 18830 Road 112

City/State/Zip: Tulare, CA 93274

Telephone No.: 559-688-1731 E-mail Address: jscullor@ucdavis.edu

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	102
Committee:	Lab

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

To eliminate some tests that are currently not being conducted on Grade A Non Fat Dry Milk from the table in Section 7 of the PMO. Also this proposal will add the requirements to sample and test other dry milk products such as MPC and milk permeate powders.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

Currently may of the states are not currently conducting these tests. FDA has concluded that since there are no validated and certified tests for these they are not debiting for the lack of these tests being completed. They are more for the standard of identity rather than quality or safety.

C. Proposed Solution

Changes to be made on page(s): 30 of the (X - one of the following):

X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

GRADE "A" NONFAT DRY MILK AND DRY MILK PRODUCTS		No More Than:
	~~Butterfat~~.....	~~1.25%~~
	~~Moisture~~.....	~~4.00%~~
	~~Titratable Acidity~~.....	~~0.15%~~
	~~Solubility Index~~.....	~~1.25mL~~.
	Bacterial Estimate.....	30,000 per gram
	Coliform.....	10 per gram
	~~Scorched Particles disc B~~.....	~~15.0 per gram~~

Name: Mike Wiggs

Agency/Organization: Idaho Department of Agriculture

Address: PO Box 790

City/State/Zip: Boise, Idaho 83701

Telephone No.: 208-736-3077 E-mail Address: mike.wiggs@agri.idaho.gov

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	103
Committee:	Lab

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

This Proposal addresses proposed changes to Table 1. Chemical, Physical, Bacteriological, and Temperature Standards within Section 7. Standards for Grade "A" Milk and Milk Products of the 2009 PMO. It specifically addresses changes to the standards for Grade "A" Nonfat Dry Milk (NFDM) by proposing to eliminate the quality testing standards, lowering the bacterial limit from 30,000 per gram to 10,000 per gram to be consistent with USDA's bacterial limit for Extra Grade NFDM, and adds "Dry Milk and Milk Products" to this header. This addition would resolve an outstanding oversight in Table 1 of not making reference to the bacteriological and coliform testing of other dry milk and milk products, which are required, i.e., dry whole milk, dry cream, etc.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

This Proposal makes corrections to Table 1 and proposes to delete the quality standards identified for nonfat dry milk and milk products. During check ratings it was identified that many States were not requiring all of the quality standards tests for nonfat dry milk to be conducted and the PMO does not address regulatory action that would be required if the quality standards were not met.

This Proposal is also proposing to decrease the bacterial limit standard from 30,000 per gram to 10,000 per gram. This standard would be consistent with USDA's bacterial standards for Extra Grade NFDM. Drying plants that are drying both Grade "A" and Extra Grade NFDM are already complying with the 10,000 per gram standard. Surveys of a few States (CA, MN, WI and NY) indicated that very few, if any, of the previous bacteriological results would have exceeded the 10,000 per gram proposed new standard for Grade "A" NFDM or Grade "A" dry milk and milk products.

Also, "Dry Milk and Milk Products" are to be added to this header, which would resolve an outstanding oversight in the PMO in making reference to the bacteriological and coliform testing of other dry milk and milk products, i.e., dry whole milk, dry cream, etc. These other Grade "A" dry milk and milk products, as defined by the PMO, are required to be sampled and tested in accordance with Section 6; however, through an oversight they have not been properly identified in Table 1. States are routinely testing these Grade "A" dry milk and milk products for bacteria and coliform in accordance with Section 6 of the PMO and the laboratory test results have always been reviewed and utilized in the calculation of Enforcement Ratings when conducting State ratings and FDA check ratings. For these Grade "A" dry milk and milk products, test methodologies for bacteria and coliform have been validated by FDA and accepted by the NCIMS.

C. Proposed Solution

Changes to be made on page(s): 30 of the (X - one of the following):

X 2009 PMO _____ 2009 EML

_____ 2009 MMSR _____ 2400 Forms

_____ 2009 Procedures _____ 2009 Constitution and Bylaws

~~Strike through~~ text to be deleted and underline text to be added.

*Make the following changes to the **2009 PMO**.*

SECTION 7. STANDARD FOR GRADE "A'" MILK AND MILK PRODUCTS

Table 1. Chemical, Physical, Bacteriological, and Temperature Standards

Page 30:

GRADE "A" NONFAT DRY MILK AND DRY MILK AND MILK PRODUCTS		~~No More Than~~ Not to Exceed:
	~~Butterfat.....~~	~~1.25%~~
	~~Moisture.....~~	~~4.00%~~
	~~Titratable Acidity.....~~	~~0.15%~~
	~~Solubility Index.....~~	~~1.25 mL~~
	Bacterial Limit.....	~~30,0000~~ 10,000 per gram
	Coliform.....	10 per gram
	~~Scorched Particles disc B.....~~	~~15.0 per gram~~

Name: CFSAN

Agency/Organization: Food and Drug Administration

Address: 5100 Paint Branch Parkway

City/State/Zip: College Park, MD 20740

Telephone No.: (301) 436-2175 E-mail Address: Robert.Hennes@fda.hhs.gov

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	104
Committee:	Lab

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

The American Dairy Products Institute (ADPI), national trade association of the processed dairy products industry, represents domestic and international manufacturers of dry milks (including nonfat dry milk), evaporated milks, whey products and cheese. Accordingly, ADPI is an interested party in this matter and submits the following problem:

Grade A Pasteurized Milk Ordinance - 2009 Revision

Table 1. Chemical, Physical, Bacteriological and Temperature Standards

- We request that the bacterial limit for Grade "A" Nonfat Dry Milk (NDM) be reduced **from 30,000 to 10,000/g.**

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

In 2000, ADPI changed its Grade Standards to specify a Standard Plate Count (bacterial estimate) of not greater than **10,000/g** for Extra Grade Nonfat Dry Milk (NDM).

The Institute requested that USDA consider similar changes to the United States Standards for Grades of Nonfat Dry Milk (Spray Process). The agency has taken such an action and the maximum bacterial count of 10,000/g for U. S. Extra Grade Nonfat Dry Milk became effective on February 2, 2001. Therefore the FDA standard of 30,000 is inconsistent with the USDA & Industry standard as reported by the ADPI Bulletin 916, "Standards for Grades of Dry Milks Including Methods of Analysis."

This difference in bacterial counts has created confusion in the domestic market as well as in the export market. The term Grade "A" is misdescriptive as it doesn't represent the highest quality NDM in terms of Standard Plate Count.

In terms of safety, a food with a lower bacterial count suggests a safer product; therefore, the term "Grade A" should connote the best (i.e., lowest) bacterial standard.

C. Proposed Solution

Changes to be made on page(s): 30 of the (X - one of the following):

X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

*Make the following changes to the **2009 PMO**.*

~~Strike through~~ text to be deleted and underline text to be added.

SECTION 7. STANDARD FOR GRADE "A'" MILK AND MILK PRODUCTS

Table 1. Chemical, Physical, Bacteriological, and Temperature Standards

Page 30:

GRADE "A" NONFAT DRY MILK		No More Than:
	Butterfat.....	1.25%
	Moisture.....	4.00%
	Titratable Acidity.....	0.15%
	Solubility Index.....	1.25 mL
	Bacterial Limit.....	~~30,0000~~ 10,000 per gram
	Coliform.....	10 per gram
	Scorched Particles disc B.....	15.0 per gram

Name: Dan Meyer

Agency/Organization: American Dairy Products Institute (ADPI)

Address: 116 N. York St., Ste. 200

City/State/Zip: Elmhurst, IL 60126

Telephone No.: 630-53-8700 E-mail Address: dmeyer@adpi.org

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	105
Committee:	Tech/Scientific

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

The purpose of this proposal is to provide language under Item 1r of the PMO for the allowance of quartermilker use under circumstances where public health would not be jeopardized.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

Some mastitis pathogens are self-limiting and the animal "self-cures" or the infection may not otherwise be responsive to antibiotic therapy. Because of concern over the potential of increasing antimicrobial resistance, antibiotic therapy is more often discouraged except for those cases where it is likely to be beneficial for the animal. This approach may reduce the chance of violative milk or tissue residue. Using a quartermilker to harvest the abnormal milk from untreated cows while offering the uncontaminated, uninfected milk of the other three quarters for human consumption provides a humane way to deal with abnormal, potentially unresponsive quarters and extend the useful life of the animal without jeopardizing public health.

Review of scientific literature (M. Guélat-Brechbuehl et al. *Veterinary Record* 2010 167: 211-215; K.A. Newman *et al. Journal of Dairy Research* 77:99–106; M.D. Apparao *et al. J. Dairy Sci.* 92:2589–2597) indicates that the common contagious mastitis pathogens infect quarters of other animals in the herd through vectors such as contaminated hands and teat cup liners. Liner slips causing a "reverse droplet impact" can spread contagious mastitis to other quarters of the same animal through the milking process. The use of a quartermilker in untreated cows eliminates the possibility of "reverse droplet impact" since the liner of abnormal quarter is not in any way connected to the milk claw. Using a separate liner with the quartermilker will limit

the spread of infection through a contaminated liner.

There is no evidence in scientific literature to suggest that most common mastitis pathogens infect other quarters of an animal by crossing the "blood/milk barrier." Although an animal may have one infected quarter, other quarters can and often remain uninfected. This concept is generally recognized in the dairy industry. Mastitis studies almost always address mastitis infections on a "quarter" basis rather than a "cow" or "animal" basis. The uninfected or normal appearing quarters are acceptable for human consumption provided that they are not otherwise contaminated. In an instance where a pathogen may be in a quarter not showing any clinical signs of infection, there is essentially no difference in offering milk from these quarters for human consumption than from any other subclinically infected quarter in the herd.

C. Proposed Solution

Changes to be made on page(s): 31-32 of the (X - one of the following):

X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

ITEM 1r. ABNORMAL MILK

Quarters of lactating ~~Lactating~~ animals which show evidence of the secretion of milk with abnormalities in ~~one (1) or more quarters~~, based upon bacteriological, chemical, or physical examination, shall be milked last or with separate equipment and the milk shall be discarded provided that milk from the remaining quarters being offered for sale is fit for human consumption. Lactating animals producing contaminated milk, that is, lactating animals which have been treated with, have consumed chemical, medicinal or radioactive agents, which are capable of being secreted in the milk and which, in the judgment of the Regulator Agency, may be deleterious to human health, shall be milked last or with separate equipment and the milk disposed of as the Regulatory Agency may direct. (For applicability to Automatic Milking Installations (AMIs), refer to Appendix Q.)

PUBLIC HEALTH REASON

The health of lactating animals is a very important consideration because of a number of diseases of lactating animals, including salmonellosis, staphylococcal infection and streptococcal infection, may be transmitted to man through the medium of milk. The organisms of most of these diseases may get into the milk either directly from the udder or indirectly through infected body discharges which may drop, splash or be blown into the milk. Bovine mastitis is an inflammatory and, generally, highly communicable disease of the bovine udder. Usually, the inciting organism is a streptococcus of bovine origin (type B), but a staphylococcus or other infectious agent often causes the disease. Occasionally lactating animal's udders become infected with hemolytic streptococcus of human origin, which may result in milkborne epidemics of scarlet or septic sore throat. The toxins of staphylococci and

possibly other organisms in milk may cause severe gastroenteritis. Some of these toxins are not destroyed by pasteurization.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. Milk from lactating animals being treated with medicinal agents, which are capable of being secreted in the milk, is not offered for sale for such a period as is recommended by the attending veterinarian or as indicated on the package label of the medicinal agent.

2. Milk from lactating animals treated with or exposed to insecticides, not approved for the use on dairy animals by the EPA, is not offered for sale.

3. The Regulatory Agency requires such additional tests for the detection of milk with abnormalities, as they deem necessary.

4. Bloody, stringy, off-colored milk, or milk that is abnormal to sight or odor, is so handled and disposed of as to preclude the infection of other lactating animals and the contamination of milk utensils.

5. Quarters of lactating ~~Lactating~~ animals secreting milk with abnormalities are milked last or in separate equipment, which effectively prevents the contamination of the wholesome supply. Milking equipment used on animals with abnormalities in their milk is maintained clean to reduce the possibility of re-infecting or cross infection of the dairy animals.

6. Equipment, utensils and containers used for the handling of milk with abnormalities are not used for the handling of milk to be offered for sale, unless they are first cleaned and effectively sanitized.

7. Processed animal waste derivatives, used as a feed ingredient for any portion of the total ration of the lactating dairy animal, have been:

    a. Properly processed in accordance with at least those requirements contained in the Model Regulations for Processed Animal Wastes developed by the Association of American Feed Control Officials; and

    b. Do not contain levels of deleterious substances, harmful pathogenic organisms or other toxic substances, which are secreted in the milk at any level, which may be deleterious to human health.

8. Unprocessed poultry litter and unprocessed recycled animal body discharges are not fed to lactating dairy animals.

Name: Jamie Jonker

Agency/Organization: National Milk Producers Federation

Address: 2101 Wilson Blvd, Suite 400

City/State/Zip: Arlington, Virginia 22201

Telephone No.: 703-243-6111 E-mail Address: jjonker@nmpf.org

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	106
Committee:	Hauling

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

Allows for additional alternatives for the direct loading of milk on a dairy farm by utilizing stubbed piping outside of the milkhouse wall as well as a transfer hose through the milkhouse hose port.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

As dairy farms increase in size the direct loading of milk becomes more of a financially feasible option versus the milkhouse bulk milk tank. The current method of direct loading allowed for in the PMO has proven effective and has demonstrated that milk can be directly loaded onto a trailer in a safe and sanitary manner. One of the problems noted with the current method, however, is the inability in many cases to consistently provide an adequate seal around the back of the tanker to protect the milkhouse from the outside.

This proposal provides for safe and sanitary direct load alternatives that can be used while protecting the milkhouse from outer openings as well as the protection of the transfer hose connection to the tanker.

C. Proposed Solution

Changes to be made on page(s): 36-40 of the (X - one of the following):

X 2009 PMO 2009 EML

_____ _____

_____ 2009 MMSR _____ 2400 Forms

_____ 2009 Procedures _____ 2009 Constitution and Bylaws

2009 PMO, Pages36-37:

ITEM 5r. MILKHOUSE - CONSTRUCTION AND FACILITIES

A transportation tank may be used for the cooling and/or storage of milk on the dairy farm. Such tank shall be provided with a suitable shelter for the receipt of milk. Such shelter shall be adjacent to, but not a part of, the milkhouse and shall comply with the requirements of the milkhouse with respect to construction items; lighting; drainage; insect and rodent control; and general maintenance. In addition, the following minimum criteria shall be met:

~~1~~a. An accurate, accessible temperature-recording device.....
~~2~~b. Temperature-recording charts shall be maintained.....
~~3~~c. The milk shall be sampled at the direction of.....
~~4~~d. The milk tank truck shall be effectively agitated.....

When the Regulatory Agency determines conditions exist whereby the milk tank truck can be adequately protected and sampled without contamination, a shelter need not be provided if the following minimum criteria are met:

~~1~~a. The milk hose connection is accessible to, and made from within, the milkhouse. The milk hose connection to the milk tank truck is completely protected from the outside environment at all times. In the case of direct loading of milk from the milkhouse to the transportation tank it shall be done in accordance with Item 5r, ADMINISTRATIVE PROCEDURES #15.
~~2~~b. To assure continued protection of the milk,.....
~~3~~c. The milk tank truck shall be washed and sanitized.....
~~4~~d. An accurate, accessible temperature-recording device shall be installed.....
~~5~~e. Temperature-recording records shall be maintained.....
~~6~~f. The milk shall be sampled at the direction of the Regulatory Agency,.....
~~7~~g. The milk tank truck shall be parked.....

2009 PMO, Pages 39 – 40;

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

~~13~~12. Water under pressure is piped into the milkhouse.
~~14~~13. Each milkhouse is provided with facilities for heating.....
~~15~~14. The milkhouse is equipped with a wash-and-rinse vat.....
~~12~~15. The transfer of milk from a bulk milk tank or the direct loading of milk from the milkhouse to a bulk milk pickup tanker is through a hose port located in the milkhouse wall. The port shall be fitted with a tight door, which shall be in good repair. It shall be kept closed except when the port is in use. An easily cleanable surface shall be constructed under the hose port, adjacent to the outside wall and sufficiently large to protect the milk hose from con-

tamination.
Provided, milk can be transferred from a bulk milk tank or directly loaded from the milkhouse to a bulk milk pickup tanker by stubbing the milk transfer and associated CIP cleaned lines outside the milkhouse wall, provided:.....

When the Regulatory Agency determines conditions exist whereby the milk tank truck can be adequately protected and sampled without contamination, a shelter need not be provided if the following minimum criteria are met:

a. The milk hose connection is accessible to, and made from within, the milkhouse. The milk hose connection to the milk tank truck is completely protected from the outside environment at all times. In the case of the direct loading of milk from the milkhouse to the transportation tank it shall be done in accordance with Item5r, ADMINISTRATIVE PROCEDURES #15.

Name: Peggy Gates, Program Manager, Dairy Regulatory Division

Agency/Organization: Georgia Department of Agriculture

Address: 19 Martin Luther King Drive

City/State/Zip: Atlanta, GA 30334

Telephone No.: 404 656-3625 E-mail Address: Peggy.Gates@agr.georgia.gov

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	107
Committee:	

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

All equipment installed in Grade-A dairy farms and processing plants must comply with the construction and design criteria of the PMO. One of the guidance documents that should be used in assessing equipment is titled "Milk and Milk Product Equipment: A Guideline for Evaluating Construction", published by the FDA. 3-A Sanitary Standards should also be used as guidance in determining compliance. The PMO references 3-A Standards in several sections in the form of a "NOTE". The wording of the "NOTE" should specify that 3-A Sanitary Standards and the FDA Equipment Guideline should be used as guidance in evaluating all equipment for compliance with the PMO.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

The PMO states that "Equipment manufactured in conformity with 3-A Sanitary Standards complies with the sanitary design and construction standards of this Ordinance". For equipment not displaying the 3-A Symbol, the 3-A Standards and FDA Equipment Guideline should be used as guidance for dairy plant and farm inspectors. This may already be implied but the Proposal provides clarification that Regulatory Agencies should use the 3-A Standards and FDA Guideline when evaluating dairy equipment.

C. Proposed Solution

Changes to be made on page(s): 45 and 66 of the (X - one of the following):

X 2009 PMO 2009 EML

	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

Add to the "NOTE:" sections of Item 9r and 11p, the following sentence after, "Equipment manufactured in conformity with 3-A Sanitary Standards complies with the sanitary design and construction standards of this Ordinance. The 3-A Sanitary Standards and FDA document titled "Milk and Milk Product Equipment: A Guideline for Evaluating Construction" should be used as guidance for all applicable dairy equipment in determining compliance with this section."

Name: Kenneth Anderson

Agency/Organization: Harold Wainess & Associates, Inc

Address: 2045 Dunhill Court

City/State/Zip: Arlington Heights, IL 60004

Telephone No.: 847/259-6400 E-mail Address: Ken.Anderson@HaroldWainess.com

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	108
Committee:	Apdx N

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

Remove and exclude expired drugs from the dairy premises and clarify that expired drugs are not used to treat dairy animals.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

The use of expired drugs on dairy farms is widespread. Dairy producers purchase drugs from their veterinarian and store left over drugs in the medicine cabinets. These drugs are then available when another animal appears to have similar symptoms and producers decide treatment and dosage themselves without the proper and necessary veterinary-client-patient relationship. Expired drug use contributes to the misuse of drugs in food-producing dairy animals and contributes to violative residues. Removing expired drugs from the dairy premises will clean out farm medicine cabinets, remove old unapproved drugs from use, replace expired products with worn labels that no longer have clear directions for use and cause producers to communicate more with their veterinarian. Veterinarians will have an increased client-patient interaction on the dairy farm and be more involved in the treatment and diagnosis of conditions that warrant drug use.

C. Proposed Solution

Changes to be made on page(s): Page 51 of the (X - one of the following):

X 2009 PMO 2009 EML

_____	2009 MMSR	_____	2400 Forms
_____	2009 Procedures	_____	2009 Constitution and Bylaws

Modify the 2009 PMO, page 51, add:
7. Drugs are stored in such a manner that they cannot contaminate the milk or milk product-contact surfaces of the containers, utensils or equipment.
8. Expired animal drugs are not to be used to treat dairy animals and are not to be stored in the milkhouse, milking barn, stable or parlor.

Name:	Nancy Grana		
Agency/Organization:	Wisconsin Department of Agriculture, Trade and Consumer Protection, Division of Food Safety		
Address:	2811 Agriculture Drive, P.O. Box 8911		
City/State/Zip:	Madison, WI 53708-8911		
Telephone No.:	715-669-3388	E-mail Address:	nancy.grana@wisconsin.gov

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	109
Committee:	

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

This proposal would allow regulatory milk plant water samples to be collected by industry personnel under the approval and direction of the regulatory agency

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

There is continued loss of resources such as staff and funding issues impact all participants of the Interstate Milk Shipment Conference. By providing more flexibility to the regulatory agency, state programs will be better able to meet and maintain the requirements of the IMS program.

The collection of raw milk producer samples under the direction of the regulatory agency is allowed for in Section 6 of the 2009 PMO as well as vitamin samples for assay analysis.

Under Appendix J.- Standards For The Fabrication Of Single-Service Containers And Closures For Milk And Milk Products, Single Service Container plants that are located within or outside of the United States are required to collect and have analyzed single service containers as outlined in Section C. of Appendix J. These container collections are not required to be conducted by a regulatory agency and yet the collection and analysis of such single service containers by the industry have been done successfully over the years.

Allowing for similar raw milk producer sampling protocols for plant water samples with regulatory agency oversight will provide for flexibility in the management of regulatory resources without impacting public health protection.

C. Proposed Solution			
Changes to be made on page(s):	61	of the (X - one of the following):	
_____	2009 PMO	_____	2009 EML
_____	2009 MMSR	_____	2400 Forms
_____	2009 Procedures	_____	2009 Constitution and Bylaws

~~Strike out~~ text to be deleted and underline text to be added.

ITEM 7p. WATER SUPPLY

This item is deemed to be satisfied when: .....

7. Samples for bacteriological testing of individual water supplies are taken upon the initial approval of the physical structure; each six (6) months thereafter; and when any repair or alteration of the water supply system has been made. Samples shall be taken ~~by~~ under the direction of the Regulatory Agency and examinations shall be conducted in an official laboratory. To determine if water samples have been taken at the frequency established in this Section, the interval shall include the designated six (6) month period plus the remaining days of the month in which the sample is due

Name:	Claudia G. Coles WA Food Safety Manager & Antone Mickelson WDIPAC Chair		
Agency/Organization:	Washington State Department of Agriculture & Washington Dairy Inspection Program Advisory Committee		
Address:	1111 Washington Street PO Box 42560		
City/State/Zip:	Olympia, Washington 98504-2560		
Telephone No.:	360-902-1905 509-952-6455	E-mail Address:	ccoles@agr.wa.gov antone.mickelson@darigold.com

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	110
Committee:	Scientific

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

This proposal makes changes to section 12p to allow for the extended storage time after culturing and "breaking" of cultured products within the same vat providing conformity between section 17p and section 12p. Currently the PMO does not state that the requirements in 17p are specific to cup-set products, however cup-set products has been interpreted.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

Item 17p Cooling of Milk and Milk Products addresses the concern and ability to hold cultured products (within the specified pH range) above 7°C (45°F) for the purpose of packaging and "setting" the product in the cup as long as the finished product is cooled to 7°C (45°F) or less within a specified time limit. This will allow for a less viscous product to be processed and packaged in a more fluid state, and then build the finished body texture as the product sets in the cup during cool-down.

In a vat-set yogurt the finished body is built within the tank at the time of culturing and cooling. At the point where the product reaches Final Processing, which is the desired pH "break" point, the agitation required to rapidly cool the product to 7°C (45°F) or less in the tank can shear the product, causing undesirable body texture.

Currently, 12p requires that all tanks used for storage of Milk and Milk Products shall be cleaned and emptied at least every 72 hours. Through the research that was completed and submitted to justify the sanitary condition and protection of Public Health by allowing cultured products (as defined in 17p) to be slowly cooled to 7°C (45°F) in a cup, it is safe to say that this same public health protection would be valid in a clean and sanitized tank, as

long as the pH and time/temperature conditions are met within the tank.

This submission is to add the same qualifications to section 12p to allow for product to be held in a processing tank longer than 72 hours, but not longer than the established cool-down time limits already established in 17p.

C. Proposed Solution			
Changes to be made on page(s):	66-68	of the (X - one of the following):	
X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

Make the following changes to the 2009 Grade "A" Pasteurized Milk Ordinance.

~~Strike out~~ text to be deleted and underlined text to be added.

PMO Page 66 to 68:

ITEM 12p. CLEANING AND SANITIZING OF CONTAINERS AND EQUIPMENT

The product-contact surfaces of all multi-use containers, utensils and equipment used in the transportation, processing, condensing, drying, packaging, handling, and storage of milk or milk products shall be effectively cleaned and shall be sanitized before each use. Provided, that cloth-collector systems used on dryers shall be cleaned and sanitized or purged at intervals and by methods recommended by the manufacturer and approved by the Regulatory Agency. Provided further, that piping, equipment and containers used to process, conduct or package aseptically processed milk and milk products, beyond the final heat treatment process, shall be sterilized before any aseptically processed milk or milk product is packaged and shall be re-sterilized whenever any non-sterile product has contaminated it.

All tanks and silos used for culturing acidified milk products, meeting the pH requirements of 17p, shall be exempt from the 72 hour storage requirement as long as all tanks/silos are equipped with a 7-day temperature recording chart that complies with Appendix H. IV. The following acidified products may be stored in tanks/silos for up to the time allotted for the cooling of cultured finished products in 17p as long as the milk products are cooled to 7°C (45°F) or less prior to the expiration of time given for final packaged (filled) product cooling as required in section 17p.

1. Cultured sour cream at all milkfat levels with a pH of 4.70 or below and cooled to 7°C (45°F) or less within one hundred sixty eight (168) hours of Final Processing;
2. Acidified sour cream at all milkfat levels with a pH of 4.60 or below and cooled to 7°C (45°F) or less within one hundred sixty eight (168) hours of Final Processing;
3. All yogurt products at all milkfat levels with an initial pH of 4.80 or below at filling, with a

pH of 4.60 or below within twenty-four (24) hours of filling* and cooled to 7°C (45°F) or less within ninety-six (96) hours of Final Processing; and

4. Cultured buttermilk at all milkfat levels with a pH of 4.60 or below and cooled to 7°C (45°F) or less within twenty-four (24) hours of Final Processing.

PUBLIC HEALTH REASON

Milk and milk products cannot be kept clean and safe, if permitted to come into contact with containers, utensils and equipment that have not been properly cleaned and sanitized.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. All multi-use containers and utensils are thoroughly cleaned after each use and all equipment is thoroughly cleaned at least once each day used, unless the Regulatory Agency has reviewed and accepted information, in consultation with FDA, supporting the cleaning of multi-use containers and utensils at frequencies extending beyond one (1) day or seventy-two (72) hours in the case of storage tanks, or forty-four (44) hours in the case of evaporators, which are continuously operated. Supporting information shall be submitted to and approved by the Regulatory Agency prior to initiating the qualification period if required. Finished product produced during an extended run must meet all applicable requirements of Section 7 of this *Ordinance*. Any significant equipment or processing changes shall be communicated to the Regulatory Agency, and may result in a re-verification of the extended run proposal, if it is determined that the change could potentially affect the safety of the finished milk or milk product(s).

The supporting information may include but is not limited to:

a. Statement of proposal, including desired cleaning frequency.
b. Product and equipment description.
c. Intended use and consumers.
d. Distribution and storage temperatures of product.
e. Diagram of process of interest.
f. Process parameters, including temperature and times.
g. Hazard evaluation and safety assessment.
h. Review of equipment for sanitary design.
i. When indicated by a hazard evaluation and safety assessment, a plan for initial qualification shall be developed to address identified critical process parameters.

Otherwise, storage tanks shall be cleaned when emptied and shall be emptied at least every seventy-two (72) hours. Records must be available to verify that milk storage in these tanks does not exceed seventy-two (72) hours. These records shall be available for at least the previous three (3) months or from the time of the last regulatory inspection, whichever is longer. In the case of pasteurized storage tanks, which are CIP cleaned at intervals of less than seventy-two (72) hours, the CIP cleaning records required under Item 2.b. of this Section shall be considered adequate. Storage tanks, which are used to store raw milk or milk products or heat-treated milk products longer than twenty-four (24) hours and silo tanks used for the storage of raw milk or milk products or heat-treated milk products shall be equipped with a seven (7) day temperature-recording device complying with the specifications of Appendix H.

IV. Electronic records that comply with the applicable provisions of Appendix H. IV and V, with or without hard copy, may be used in place of the seven (7) day temperature-recording records.

All tanks and silos used for culturing acidified milk products, meeting the pH requirements of 17p, shall be exempt from the 72 hour storage requirement as long as all tanks/silos are equipped with a 7-day temperature recording device complying with the specifications of Appendix H.IV. The following acidified products may be stored in tanks/silos for up to the time allotted for the cooling of cultured finished products in 17p as long as the milk products are cooled to 7°C (45°F) or less prior to the expiration of time given for final packaged (filled) product cooling as required in section 17p.

1. Cultured sour cream at all milkfat levels with a pH of 4.70 or below and cooled to 7°C (45°F) or less within one hundred sixty eight (168) hours of Final Processing;
2. Acidified sour cream at all milkfat levels with a pH of 4.60 or below and cooled to 7°C (45°F) or less within one hundred sixty eight (168) hours of Final Processing;
3. All yogurt products at all milkfat levels with an initial pH of 4.80 or below at filling, with a pH of 4.60 or below within twenty-four (24) hours of filling* and cooled to 7°C (45°F) or less within ninety-six (96) hours of Final Processing; and
4. Cultured buttermilk at all milkfat levels with a pH of 4.60 or below and cooled to 7°C (45°F) or less within twenty-four (24) hours of Final Processing.

Otherwise provided, evaporators shall be cleaned at the end of a continuous operation, not to exceed forty-four (44) hours, and records must be available to verify that the operation time does not exceed forty-four (44) hours.

Drying equipment, cloth-collector systems, packaging equipment and multi-use dry milk products and dry whey storage containers are cleaned at intervals and by methods recommended by the manufacturer and approved by the Regulatory Agency. Such methods may include cleaning without water by use of vacuum cleaners, brushes, or scrapers. After cleaning, such equipment is sanitized by a method approved by the Regulatory Agency. Cloth collector systems and all dry product-contact surfaces downstream from the dryer shall be sanitized or purged at intervals and by methods recommended by the manufacturer and approved by the Regulatory Agency. Storage bins used to transport dry milk or milk products shall be dry cleaned after each usage and washed and sanitized at regular intervals.

Name:	Mike Melville		
Agency/Organization:	Publix Super Markets, Inc.		
Address:	777 S.W. 12th Avenue		
City/State/Zip:	Deerfield Beach, FL 33442		
Telephone No.:	954 429-0122	E-mail Address:	mike.melville@publix.com

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	111
Committee:	Hauling

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

To ensure milk tank trucks are washed properly in a timely manner.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

In the milk hauling industry it is important to have a clean tank in a timely manner as milk is moving longer distances and tank trucks are not always able to be washed when unloaded. For public health purposes it would be in the best interest to have milk tank trucks washed after being unloaded at a milk plant, transfer or receiving station. It ensures that soils do not build up within the tank. Delays in washing a tank could create soil buildup inside the tank. This proposal better ensures that milk trucks will be properly washed as specified in the PMO.

C. Proposed Solution

Changes to be made on page(s): 67 of the (X - one of the following):

X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

NOTE: Appendix F. contains additional information on dry cleaning of drying equipment, packaging equipment, and dry milk product and dry whey storage containers.

All milk tank trucks that transport Grade "A" milk and milk products, shall be washed and sanitized at a permitted milk plant, receiving station, transfer station, or milk tank truck cleaning facility. The milk tank truck shall be cleaned and sanitized prior to its first use. When the time elapsed after cleaning and sanitizing, and before its first use, exceeds ninety-six (96) hours the tank must be re-sanitized. The milk tank truck shall be cleaned and sanitized by the milk plant, transfer or receiving station, or permitted plant after unloading Grade "A" milk or milk products unless Appendix B item IV 3.b(3) is applicable.

Name: Cherie Tuhus

Agency/Organization: International Milk Haulers Association

Address: 5307 Indigo Way

City/State/Zip: Middleton, WI 53562

Telephone No.: 608-354-7110 E-mail Address: Cherie@milkhauler.org

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	112
Committee:	Scientific

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

I propose multi-serve should be allowed up to 4 grams of residual, sterile water or chemistry (target 3 grams) and single serve up to 3 grams (target 2 grams); while still abiding by the current legal concentration limits, a mix of a 0.5% hydrogen peroxide, with the current test method.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

To improve milk's shelf life and consumer safety, we should use technology to sanitize and sterilize both bottles and caps with peracetic acid based hydrogen peroxide products (example Vortexx, Divosan Activ, Oxonia Active or similar). This small change in legislation will make a huge impact in the dairy industry bringing milk from a 12-19 day shelf life to a 25-55 day shelf life. This would allow dairies to expand their customer base and revolutionize the dairy industry!

C. Proposed Solution

Changes to be made on page(s): 72 of the (X - one of the following):

X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

Additional text to be added to page 72 on Cleaning and Sanitizing of Containers
c-1 -
To extend milk's shelf life the bottler has the option of using technology that sanitizes or sterilizes both glass and/or plastic bottles and caps with peracetic acid based hydrogen peroxide products (example Vortexx, Divosan Activ, Oxonia Active or similar). Immediately prior to filling you may choose to rinse with a water/chemistry solution using inverted draining leaving up to 4 grams of residual, sterile water or chemistry (target 3 grams or less) and single serve up to 3 grams (target 2 grams or less); while still abiding by the current legal concentration limits, a mix of a .5% hydrogen peroxide, with the current test method.

Name:	Ben Fogg		
Agency/Organization:	Fogg Filler		
Address:	3455 John F Donnelly Dr		
City/State/Zip:	Holland, MI 49424		
Telephone No.:	616-405-9443	E-mail Address:	bfogg@foggfiller.com

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	113
Committee:	Tech

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

This Proposal updates the requirements within Item 15p(B)-Protection from Contamination of the PMO for single-bodied double seat valves, used to separate cleaning solutions from product circuits, to be consistent with the 3-A Standard for Double Seat Mixproof Valves (85-01). It also provides a useful clarification and a simplification of the low pressure gravity drain application requirements cited within Item 15p(B).

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

3-A Sanitary Standards, Inc. (3-A SSI) has updated and published a new Standard for Double-Seat Mixproof Valves (85-01). The new 3-A Standard allows for an atmospheric vent opening of less than the largest pipe diameter of the double seat valve. This criteria is provided and requires that data be submitted indicating that the maximum pressure in the space between the two (2) valve seats is equivalent to or less than the maximum pressure in the space between the two (2) blocking seats of two (2) automatically controlled compression type valves (three (3)-way valve to the drain and a two (2)-way valve separating product lines from cleaning and sanitizing solution lines). Existing PMO language limits the atmospheric vent opening to a size equal to the largest pipeline feeding the valve. This Proposal will make the PMO requirements for single-bodied double seat valves to be consistent with current 3-A Sanitary Standards requirements.

C. Proposed Solution			
Changes to be made on page(s):	77 and 78	of the (X - one of the following):	
X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

~~Strike through~~ text to be deleted and underline text to be added.

*Make the following changes to the **2009 PMO**.*

ITEM 15p. PROTECTION FROM CONTAMINATION

Page 77:

15p.(B)

1. During processing, pipelines and equipment used to contain or conduct milk and milk products shall be effectively separated from tanks or circuits containing cleaning and/or sanitizing solutions. This can be accomplished by:

a. Physically disconnecting all connection points between tanks or circuits containing cleaning and/or sanitizing solutions from pipelines and equipment used to contain or conduct milk or milk products; or

b. Separation of all connection points between such circuits by at least two (2) automatically controlled valves with a drainable opening to the atmosphere between the valves; or by a single-bodied double seat mixproof valve, with a drainable opening to the atmosphere between the seats, if:

(1) The drainable opening to the atmosphere (vent) is equal to the largest pipeline ~~feeding the valve(s)~~ connected to the mixproof valve or one (1) of the following exceptions:

i) If the cross sectional area of the vent opening is less than that of the largest pipe diameter for the double seat valve, the maximum pressure in the space between the two (2) valve seats for the double seat valve shall be equivalent to or less than the maximum pressure in the space between the two (2) blocking seats of two (2) automatically controlled compression type valves (three (3)-way valve to the drain and a two (2)-way valve separating product lines from cleaning and sanitizing solution lines); or

ii) In low pressure, gravity drain applications, i.e., cheese curd transfer lines from cheese process vats where the product line is the same size or larger than the cleaning or sanitizing solution line, the vent may be the size of the solution line and the valves or valve seats need not be position detectable. In order to accept this variation, the valve(s) must fail to the blocked position upon loss of air or power, and there shall not be any pumps capable of pushing milk or milk product, cleaning solutions, or sanitizing solutions into this valve arrangement.

(2) Both valves, and valve seats in the case of single-bodied double seat valves, are position detectable and capable of providing an electronic signal when not properly

seated in the blocked position. (Refer to Appendix H., I., Position Detection Devices.)
....

Page 78:

(7) Variations from the above specifications may be individually evaluated and found to also be acceptable if the level of protection is not compromised.

~~**For Example:** In low pressure, gravity drain applications where the product line is the same size or larger than the cleaning or sanitizing solution line, the vent may be the size of the solution line and the valves or valve seats need not be position detectable. If a common drain line is used to connect vent lines from more than one (1) block and bleed vent, such as in the case of drain lines from a series of cheese vats with a common drain for the block-and-bleed vent lines, the cross sectional area of the common drain line must be at least equal to the total cross sectional area of the lines connected to the header. Or, a common drain line of the same size as the vent may be used, if provisions are included in a fail-safe control system to sequence the use and cleaning of the vats to assure that no more than one (1) vat attached to that drain can be washed at the same time. All other criteria still apply. In order to accept this variation, the valve(s) must fail to the blocked position upon loss of air or power, and there must be no pumps capable of pushing milk or milk product, cleaning solutions, or sanitizing solutions into this valve arrangement.~~

Name: CFSAN

Agency/Organization: Food and Drug Administration

Address: 5100 Paint Branch Parkway

City/State/Zip: College Park, MD 20740

Telephone No.: (301) 436-2175 E-mail Address: Robert.Hennes@fda.hhs.gov

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	114
Committee:	Tech

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

Provides more detailed pasteurized product protection and operational criteria for a milk or milk product-to water-to-milk or milk product regenerator when used for heat exchange purposes.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

Many plants utilize milk or milk product-to water-to-milk or milk product regenerators for the purpose of exchanging heat between raw and pasteurized product. This regeneration is an efficient use of physical space, equipment and energy within the operation. Although 16p(D) establishes design and operational criteria for these types of heat-exchange systems when used within a pasteurizing or aseptic processing system, further provision for the protection of pasteurized product when using these systems is provided for in the proposed solution.

C. Proposed Solution

Changes to be made on page(s): 81 of the (X - one of the following):

X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

8. In no case shall pasteurized milk or milk products, be standardized with unpasteurized milk or milk products, unless the standardized milk or milk product is subsequently pasteurized.
9. Reconstituted or recombined milk and milk products shall be pasteurized after reconstitution or recombining of all ingredients.
10. Raw milk or milk product-to-water-to-pasteurized milk or milk product regenerators may be used for heat-exchange purposes when constructed, installed and operated such that the pasteurized milk product in the regenerator will be under greater pressure than the heat-transfer-medium in the regenerator at all times:

a) Regenerators of this type shall be constructed, installed and operated so that pasteurized milk or milk product in the regenerator will automatically be under greater pressure than the heat-transfer water in the regenerator at all times.

b) The pasteurized milk or milk product, between its outlet from the regenerator and the nearest point downstream open to the atmosphere, shall rise to a vertical elevation of 30.5 centimeters (12 inches) above the highest heat-transfer water level, downstream from the water supply tank, and shall be open to the atmosphere at this or a higher elevation.

c) The overflow of the top rim of the water supply tank shall always be lower than the lowest heat-transfer water level in the regenerator.

d) No pump or flow-promoting device which can affect the proper pressure relationships within the regenerator shall be located between the pasteurized milk or milk product outlet from the regenerator and the nearest downstream point open to the atmosphere.

e) No pump shall be located between the heat-transfer water inlet to the regenerator and the water supply tank, unless it is designed and installed to operate only when pasteurized milk or milk product is flowing through the pasteurized milk product side of the regenerator and when the pressure of the pasteurized milk or milk product is higher than the maximum pressure produced by the pump. This may be accomplished by wiring the heat-transfer water pump so that it cannot operate unless:

a. Pasteurized milk or milk product is flowing through the pasteurized milk product side of the regenerator; and

b. The pasteurized milk product pressure exceeds, by at least 6.9 kPa (1 psi), the maximum pressure developed by the heat-transfer water pump. Pressure gauges shall be installed at the heat-transfer water inlet to the regenerator and the pasteurized milk product outlet of the regenerator. The accuracy of these required pressure gauges shall be checked, by the Regulatory Agency, on installation; quarterly thereafter; and following repair or adjustment.

f) All heat-transfer water in the regenerator(s) will automatically drain freely into the water supply tank or to the floor when the heat transfer water pump(s) are shut down and the heat-transfer water connection(s) at the regenerator(s) is disconnected.

Name:	Dean Tjornehoj		
Agency/Organization:	California Dairies Inc.		
Address:	2000 North Plaza Drive		
City/State/Zip:	Visalia California, 93291		
Telephone No.:	(559)625-2200	E-mail Address:	dtjornehoj@californiadairies.com

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	115
Committee:	Tech/Scientific

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

This proposal would allow the circulating loop of a cross-flow membrane micro-filtration system to be maintained at an elevated temperature during production as an alternative to the current cooling requirements of ADMINISTRATIVE PROCEDURES #3 of Item 16p.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

ADMIN. PROCEDURES #3, b. of Item 16p currently requires milk and milk products that are to be concentrated by RO or UF membrane filtration systems to either be pasteurized prior to the filtration process or be maintained at a temperature of less than 65°F (or 70°F for less than 15 minutes). The purpose of this limitation is to restrict bacterial growth while the product is in the retentate loop of the filtration system. While this temperature requirement may be a valid safeguard for the concentrated retentate that is the desired final product of these processes, it is not necessarily applicable to cross flow membrane filtration systems in which the final product is the permeate that has passed through the filter membrane.

The major use of micro-filtration is to reduce the bacterial load of milk and milk products either for extended shelf life dairy products or for the manufacture of cheese. In these applications, the high efficiency of the filter membranes in removing bacteria (3-6 log reduction) means that any bacteria growth in the retentate loop during the normal operating time of these system (up to 10-12 hours) will be more than nullified in the product (permeate) by the removal rate of the membrane. In addition, the total number of bacteria in the retentate loop will constantly be diluted by the removal of retentate and the addition of new product feed.

Another concern has been the growth of toxin producing organisms such as Staphylococcus aureus at the elevated temperatures. Literature evidence from several sources, however, indicates that Staph aureus will only reproduce at temperatures between 45°F and 118°F, and will only produce toxin at temperatures between 57°F and 113°F. Therefore, if the temperature of the milk product in the circulating retentate loop is maintained above 120°F, both growth and toxin formation would be prohibited.

C. Proposed Solution

Changes to be made on page(s): 84 of the (X - one of the following):

X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

Make the following changes to the 2009 Grade "A" Pasteurized Milk Ordinance.

~~Strike out~~ text to be deleted and underlined text to be added

Add to Item 16p, ADMINISTRATIVE PROCEDURES:

6. Milk and/or milk products for pasteurization may be processed by micro-filtration systems prior to pasteurization, provided that;

a. prior to processing, all raw milk supplies are sampled and tested for antibiotic residues in accordance with the provisions of Appendix N.;

b. if there is a continuous, circulating retentate loop with a feed and bleed system, the following design, installation and operational criteria must be met:

(1) The micro-filtration system is designed and operated to assure that milk or milk product temperature in the circulating retentate loop is maintained at or below 18.3°C (65°F), or at or above 51.7°C (125°F) throughout the process. Provided that the product temperature may rise above 18.3°C (65°F) or fall below 51.7°C (125°F) for a period of not more than fifteen (15) minutes, further provided that should the product temperature rise above 21.1°C (70°F) or fall below 48.9°C (120°F), the product shall be either immediately diverted to the system's balance tank until the product is again below 18.3°C (65°F) or above 51.7°C (125°F), or be diverted to exit the system entirely. Diverted product that has exited the system shall be either discarded, immediately cooled to below 7°C (45°F), or immediately pasteurized;

(2) The MF system must be equipped with temperature monitoring and recording devices that comply with the applicable specifications outlined in Appendix H. of this *Ordinance*. At a minimum, milk or milk product temperature shall be monitored and recorded prior to entering the system and within the circulating retentate loop of each module.

~~6~~7. The design and operation of pasteurization equipment and all appurtenances thereto shall comply with the applicable specifications and operational procedures of Subitems (A), (B), (D) and (E).

Chuck Meek

Agency/Organization: Tetra Pak Processing Systems Americas

Address: 200 South Park Blvd.

City/State/Zip: Greenwood, IN 46143

Telephone No.: 317-885-5170 E-mail Address: chuck.meek@tetrapak.com

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	116
Committee:	

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

To require that the reading of the airspace thermometer be recorded on batch pasteurizer charts only at the start of the holding period if the airspace thermometer is a digital combination type with a continuous recording of the airspace temperature.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

Currently the airspace thermometer is required to be read and recorded on batch pasteurizer charts at the start and end of the holding period. Digital combination airspace thermometers, as approved in Appendix H, provide a continuous recording of the airspace temperature comparable to the continuous recording of the product temperature on the pasteurizer charts. The indicating thermometer is required to be read and compared to the recording thermometer at the start of the holding period. There should be no public health significance in only requiring reading the digital portion of the airspace thermometer and recording it on the chart at the start of the holding period as the continuous recording will provide documentation that the proper airspace temperature is maintained throughout the holding period.

C. Proposed Solution

Changes to be made on page(s): 102 of the (X - one of the following):

X 2009 PMO 2009 EML

_____	2009 MMSR	_____	2400 Forms
_____	2009 Procedures	_____	2009 Constitution and Bylaws

ITEM 16p.(E) PASTEURIZATION AND ASEPTIC PROCESSING RECORDS, EQUIPMENT TESTS AND EXAMINATIONS

1. **PASTEURIZATION AND ASEPTIC PROCESSING RECORDS:**

All temperature and flow rate pasteurization recording charts or alternative records, acceptable to
FDA, in place of charts shall be preserved for a period of three (3) months. Provided, that all records and recording charts for aseptic milk and milk product systems shall be retained for a period of three (3) years. The use of such charts shall not exceed the time limit for which they are designed. Overlapping of recorded data shall be a violation of this Item. The following information shall be entered on the charts or other records acceptable to FDA in place of charts as applicable:

a. **Batch Pasteurizers**:

(1) Date;
(2) Number or location of recording thermometer when more than one is used;
(3) A continuous record of the product temperature;
(4) Extent of holding period, including filling and emptying times when required;
(5) Reading of airspace thermometer, at the start of the holding period and at the end of the holding period, at a given time or reference point as indicated on the chart, provided if the airspace thermometer is a digital combination type with a continuous recording of the airspace temperature, the reading of the digital airspace thermometer shall only be required at the start of the holding period;
(6) Reading of indicating thermometer, at the start of the holding period, at a given time or reference point as indicated on the chart;
(7) Quarterly, the time accuracy of the recording thermometer, as determined

Name: Leah Keller

Agency/Organization: New Hampshire Department of Health and Human Services

Address: 29 Hazen Drive

City/State/Zip: Concord, NH 03301

Telephone No.: (603) 271-4673 E-mail Address: lkeller@dhhs.state.nh.us

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	117
Committee:	Scientific

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

To recognize the results of the scientific challenge studies conducted by the Milk Industry Foundation (MIF) in cooperation with the US Food & Drug Administration from 2005 until 2008 that demonstrated that the use of potassium sorbate or specific microbial inhibitors combined with filling cottage cheese at 55°F or less and cooling to 45°F or less within 72 hours after filling provide equal or better food safety protection that the current PMO requirement to fill cottage cheese at 45°F.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

The Milk Industry Foundation (MIF), which represents Grade "A" dairy processors, submitted proposal 126 at the 2005 NCIMS Conference, which was passed by the delegates. FDA in a July 2005 letter to the NCIMS Executive Board raised objections to this proposal (non-concur). During the September 2005 joint meeting between the NCIMS Executive Board and FDA, FDA requested that if MIF could provide some additional evidence of the safety of filling cottage cheese at temperatures of 55°F and cooling the product down to 45°F in a reasonable amount of time, FDA would consider withdrawing its non-concur position. The NCIMS Executive Board requested FDA and MIF to work together to resolve this issue.

During the latter part of 2005, MIF developed a challenge study protocol, which was accepted by FDA, to conduct laboratory trials at the University of Wisconsin and overseen by Dr. Kathy Glass. The challenge study exposed cottage cheese at 55°F to various pathogens and then cooled the cottage cheese and pathogen mixture at various rates down to 45°F. The product was sampled initially and throughout the cooling period and the level of pathogens measured. This first challenge study showed that the pH of cottage cheese was generally not low enough to

inhibit the growth of pathogens are a rate equal to or lower than the growth of pathogens in cottage cheese maintained at 45°F.

A second challenge study was conducted in 2006, using very similar protocol by Dr. Kathy Glass and this demonstrated that the use of potassium sorbate at certain concentrations in the cottage cheese was very effective in reducing or stopping the growth of pathogens inoculated into the cottage cheese. However, a number of cottage cheese processors preferred not to use potassium sorbate because of slight flavor issues in the cottage cheese.

The final challenge study (third) was conducted by Dr. Glass in 2007 & 2008, using natural microbial inhibitors. FDA reviewed and accepted the challenge study protocol, which had to be modified from the first two challenge studies to address the proper storage, mixing and addition of the various microbial inhibitors. The report of this third challenge study demonstrated that the use of microbial inhibitors added to cottage cheese filled at 55°F or less and cooled to 45°F or less within 72 hours successfully reduced the growth of pathogens in cottage cheese to a level that was equal to or lower than the growth of these same pathogens when the cottage cheese was filled at 45°F. The final report from this third challenge study was submitted to FDA for final review in January 2009. At a meeting scheduled by FDA on August 13, 2010 between MIF members, companies providing the various microbial inhibitors and Dr. Kathy Glass, who conducted all three challenge studies, it appeared that FDA's senior scientist was supportive of the premise of the third challenge study, i.e. that the use of microbial inhibitors enhance the safety of cottage cheese.

The outcome of all three of these studies provided additional scientific evidence to a large body of information in the scientific literature that cottage cheese can be safely filled at 55°F or lower and reduced in temperature to 45°F or lower within 72 hours after filling, provided that either the proper concentration of potassium sorbate or one of the specific microbial inhibitors is used.

The purpose of this proposal is to modify Section 17 of the 2009 Pasteurized Milk Ordinance to recognize the new scientific evidence on enhancing the safety of cottage cheese.

C. Proposed Solution

Changes to be made on page(s): 107 – 111 of the (X - one of the following):

XXX	2009 PMO	_____	2009 EML
_____	2009 MMSR	_____	2400 Forms
_____	2009 Procedures	_____	2009 Constitution and Bylaws

CHANGES TO ITEM 17p.-COOLING OF MILK AND MILK PRODUCTS

ITEM 17p. COOLING OF MILK AND MILK PRODUCTS

All raw milk and milk products shall be maintained at 7°C (45°F) or less until processed. All whey and whey products for condensing and/or drying shall be

maintained at a temperature of 7°C (45°F) or less; or 57°C (135°F) or greater until processed, except that acid-type whey with a titratable acidity of 0.40% or above, or a pH of 4.6 or below, is exempted from these temperature requirements.
All pasteurized milk and milk products, except the following, shall be cooled immediately prior to filling or packaging, in approved equipment, to a temperature of 7°C (45°F) or less, unless drying is commenced immediately after condensing:

1. Those to be cultured;
2. Cultured sour cream at all milkfat levels with a pH of 4.70 or below*;
3. Acidified sour cream at all milkfat levels with a pH of 4.60 or below*;
4. All yogurt products at all milkfat levels with an initial pH of 4.80 or below* at filling;
5. Cultured buttermilk at all milkfat levels with a pH of 4.60 or below*; ~~and~~
6. Cottage cheese at all milkfat levels with an initial pH of 5.2 or below*, and

~~6~~7. All condensed whey and whey products shall be cooled during the crystallization process to 10°C (50°F) or less within seventy-two (72) hours of condensing, including the filling and emptying time, unless filling occurs above 57°C (135°F), in which case, the seventy-two (72) hour time period begins when cooling is started****.

*Critical factors including, but not limited to, pH and cooling time and temperature shall be monitored and documented by the processing facility for verification by the Regulatory Agency. pH limit with a pH variance of + 0.05 units to account for reproducibility and inaccuracies in pH measurements. Formulation or processing changes that affect critical factors shall be communicated to the Regulatory Agency.

All pasteurized milk and milk products, except the following, shall be stored at a temperature of 7°C (45°F) or less and maintained thereat following filling or until further processed:

1. Cultured sour cream at all milkfat levels with a pH of 4.70 or below* and cooled to 7°C (45°F) within one hundred sixty eight (168) hours of filling**;
2. Acidified sour cream at all milkfat levels with a pH of 4.60 or below* and cooled to 7°C (45°F) within one hundred sixty eight (168) hours of filling**;
3. All yogurt products at all milkfat levels with an initial pH of 4.80 or below* at filling, with a pH of 4.60 or below within twenty-four (24) hours of filling* and cooled to 7°C (45°F) within ninety-six (96) hours of filling**; ~~and~~
4. Cultured buttermilk at all milkfat levels with a pH of 4.60 or below* and cooled to 7°C (45°F) within twenty-four (24) hours of filling**; and
5. Cottage cheese at all milkfat levels:
   a. With an initial pH of 5.2 or below* and filled at 13°C (55°F) or below and cooled to 7°C (45°F) or below within seventy-two (72) hours of filling**, if using one or a combination of more than one of the following:
      1) Inhibitor I – minimum of 0.03% Bioactive Protein I*
      2) Inhibitor D – minimum of 0.15% Fermentate D*
      3) Inhibitor E – minimum of 0.1% Fermentate E*
      4) Inhibitor E – minimum of 0.1% Fermentate E + Live Culture*
      5) Inhibitor A – minimum of 0.15% Fermentate A*
      6) Potassium sorbate - minimum of 0.06%*

*Critical factors including, but not limited to, pH, potassium sorbate concentration, microbial inhibitor concentration, ~~and~~ cooling time and temperature shall be monitored and documented by the processing facility for verification by the Regulatory Agency. pH limit with a pH variance of + 0.05 units to account for reproducibility and inaccuracies in pH measurements. Formulation or processing changes that affect critical factors shall be communicated to the Regulatory Agency.

** Temperature monitored at the slowest cooling portion, i.e., middle of the container, of the slowest cooling container, i.e., in the middle of the pallet.

All pasteurized milk and milk products to be condensed and/or dried, shall be stored at a temperature of 10°C (50°F) or less and be maintained thereat until further processed.

Every refrigerated room or tank, in which milk or milk products, whey and whey products, and condensed milk and milk products are stored, shall be equipped with an accurate indicating thermometer.

On delivery vehicles, the temperature of milk and milk products shall not exceed 7°C (45°F).

Aseptically processed milk and milk products to be packaged in hermetically sealed containers shall be exempt from the cooling requirements of this Item.

Electronic Data Collection, Storage and Reporting: The electronic storage of required cleaning records and product storage temperature records, with or without hard copy printouts, shall be acceptable, provided, the electronically generated records are readily available at the milk plant for review by the Regulatory Agency. Electronic records that comply with the applicable provisions of Appendix H., IV and V, with or without hard copy, may be used in place of the cleaning records.

PUBLIC HEALTH REASON

When milk and milk products are not cooled within a reasonable time, after being received at the milk plant, its bacterial content will be materially increased. The same reasoning applies to cooling the milk and milk products after pasteurization, unless drying is commenced immediately after condensing.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. All raw milk and milk products shall be maintained at 7°C (45°F) or less until processed, except that acid-type whey with a titratable acidity of 0.40% or above, or a pH of 4.6 or below, is exempted from these temperature requirements. Provided, that all balance or surge tanks (continuous flow with a retention time not to exceed one (1) hour) for raw milk and milk products, pasteurized milk and milk products and whey and whey products may be maintained at any temperature for up to twenty-four (24) hours.
2. All whey and whey products for condensing and/or drying are maintained at a temperature of 7°C (45°F) or less; or 57°C (135°F) or greater until processed. Storage tanks containing whey and whey product above 7°C (45°F) and below 57°C (135°F) shall be emptied, cleaned and sanitized after each four (4) hours of use or

less. ***

3. All pasteurized milk and milk products, except the following, are cooled immediately in approved equipment prior to filling or packaging to a temperature of 7°C (45°F) or less, unless drying is commenced immediately after condensing:

a. Those to be cultured;
b. Cultured sour cream at all milkfat levels with a pH of 4.70 or below*;
c. Acidified sour cream at all milkfat levels with a pH of 4.60 or below*;
d. All yogurt products at all milkfat levels with an initial pH of 4.80 or below* at filling;
e. Cultured buttermilk at all milkfat levels with a pH of 4.60 or below*; ~~and~~
f. Cottage cheese at all milkfat levels with an initial pH of 5.2 or below*, and
~~f~~g. All condensed whey and whey products shall be cooled during the crystallization process to 10°C (50°F) or less within seventy-two (72) hours of condensing, including the filling and emptying time, unless filling occurs above 57°C (135°F), in which case, the seventy-two (72) hour time period begins when cooling is started. ***

*Critical factors including, but not limited to, pH and cooling time and temperature shall be monitored and documented by the processing facility for verification by the Regulatory Agency. pH limit with a pH variance of + 0.05 units to account for reproducibility and inaccuracies in pH measurements. Formulation or processing changes that affect critical factors shall be communicated to the Regulatory Agency.

4. All pasteurized milk and milk products, except the following, shall be stored at a temperature of 7°C (45°F) or less and be maintained thereat following filling or until further processed:

a. Cultured sour cream at all milkfat levels with a pH of 4.70 or below* and cooled to 7°C (45°F) within one hundred sixty eight (168) hours of filling**;
b. Acidified sour cream at all milkfat levels with a pH of 4.60 or below* and cooled to 7°C (45°F) within one hundred sixty eight (168) hours of filling**;
c. All yogurt products at all milkfat levels with an initial pH of 4.80 or below* at filling, with a pH of 4.60 or below within twenty-four (24) hours of filling* and cooled to 7°C (45°F) within ninety-six (96) hours of filling**; ~~and~~
d. Cultured buttermilk at all milkfat levels with a pH of 4.60 or below* and cooled to 7°C (45°F) within twenty-four (24) hours of filling**, and
e. Cottage cheese at all milkfat levels:
a. With an initial pH of 5.2 or below* and filled at 13°C (55°F) or below and cooled to 7°C (45°F) or below within seventy-two (72) hours of filling**, if using one or a combination of more than one of the following:
1) Inhibitor I – minimum of 0.03% Bioactive Protein I*
2) Inhibitor D – minimum of 0.15% Fermentate D*
3) Inhibitor E – minimum of 0.1% Fermentate E*
4) Inhibitor E – minimum of 0.1% Fermentate E + Live Culture*
5) Inhibitor A – minimum of 0.15% Fermentate A*
6) Potassium sorbate - minimum of 0.06%*

*Critical factors including, but not limited to, pH, potassium sorbate concentration, microbial inhibitor concentration, ~~and~~ cooling time and temperature shall be

monitored and documented by the processing facility for verification by the Regulatory Agency. pH limit with a pH variance of + 0.05 units to account for reproducibility and inaccuracies in pH measurements. Formulation or processing changes that affect critical factors shall be communicated to the Regulatory Agency.

** Temperature monitored at the slowest cooling portion, i.e., middle of the container, of the slowest cooling container, i.e., in the middle of the pallet.

5. All pasteurized milk and milk products to be condensed and/or dried, shall be stored at a temperature of 10°C (50°F) or less and be maintained thereat until further processed. If storage tanks are used between the condenser and dryer, any such storage tank(s) containing pasteurized milk or milk products stored above 10°C (50°F) and below 57°C (135°F) shall be completely emptied and cleaned after each six (6) hours of operation or less. ***

6. Each refrigerated room in which milk and milk products are stored, except aseptically processed milk and milk products, is equipped with an indicating thermometer that complies with the applicable specifications of Appendix H. Such thermometer shall be located in the warmest zone of the refrigerated room.

7. Each storage tank shall be equipped with an indicating thermometer, the sensor of which shall be located to permit the registering of the temperature of the contents when the tank contains no more than twenty percent (20%) of its calibrated capacity. Such thermometer shall comply with the applicable specifications of Appendix H.

8. On delivery vehicles, the temperature of milk and milk products shall not exceed 7°C (45°F).

9. All surface coolers comply with the following specifications:

   a. The sections of open-surface coolers shall be so installed as to leave a gap of at least 6.4 millimeters (0.25 inches) between the header sections to permit easy cleaning.

   b. Where header ends are not completely enclosed within the cooler covers, condensation or leakage from the headers shall be prevented from entering the milk or milk product by so shaping the exposed header faces, above and below all gaps, that condensation is directed away from the tubes, and by using deflectors at the bottom of the headers; or by shortening the bottom of the headers; or by shortening the bottom trough; or by some other approved method.

   c. The location of supports of cooler sections shall prevent condensation and leakage from entering the milk or milk product.

   d. All open-surface coolers shall be provided with tight-fitting shields that protect the milk and milk product from contamination by insects, dust, drip, splash or manual contact.

10. Recirculated cooling water, which is used in coolers and heat exchangers, including those systems in which a freezing point depressant is used, is from a safe source and protected from contamination. Such water shall be tested semiannually and shall comply with the Bacteriological Standards of Appendix G. Samples shall be taken by the Regulatory Agency and examination shall be conducted in an Official Laboratory. Recirculated cooling water systems, which become contaminated through repair work or otherwise, shall be properly treated and tested before being returned to use. Freezing point depressants and other chemical additives, when used in recirculating systems, shall be non-toxic under conditions of use.

11. Recirculated cooling water contained in corrosion resistant, continuous piping, with no joints or welds, which fail to meet applicable ASME or equivalent standards in the

non-potable water contact areas, may be considered to be protected from contamination, as required above, when cooled by non-potable water flowing over the exterior of the piping, within open evaporative type cooling tower. In these systems, the recirculated cooling water piping shall be properly maintained and shall be installed so that it is at least two (2) pipe diameters above the flood rim of the cooling tower.

12. Water from an open, evaporative cooling tower may be used to cool water in an intermediate cooling media loop that will subsequently be used to cool product, provided that the water in the intermediate cooling media loop is effectively protected against infiltration and contamination by tower water at all times.

If a plate type or double/triple tube type heat exchanger is used to exchange heat between the water from the open tower and the water in the intermediate cooling media loop it must be protected by an Isolation System to assure that there is no possibility of contamination of the intermediate cooling media loop water by the tower water. The Isolation System shall include:

a. Tower water heat exchangers shall be constructed, installed and operated so that the intermediate cooling media water in the heat exchanger will automatically be under greater pressure than the open tower water in the heat exchanger at all times.

b. The tower water heat exchanger shall be effectively isolated from the tower water system and the tower water side of the heat exchanger shall drain during shut down.

c. The Isolation System shall be controlled with a pressure differential controller set to a minimum of 6.9 kPa (1 psi). Pressure sensors shall be installed at the tower water inlet to the heat exchanger and intermediate cooling water outlet of the heat exchanger. The differential pressure controller will be interwired with the related supply valves and/or pumps to automatically shut down all supply pumps and return valves in the Isolation System to a fail-
safe position to isolate the heat exchanger from the open tower water system, as would occur in a shut down or power failure.

d. The intermediate cooling water shall rise to a vertical elevation of at least 30.5 centimeters (12 inches) above the highest tower water in the tower water heat exchanger Isolation System, and shall be open to the atmosphere at this elevation. During a shut down the intermediate cooling water shall not drain from the tower water heat exchanger.

e. The Isolation System shall meet one (1) of the following:

(1) In a system with tower water supplied directly from the tower water distribution line without a balance tank, or with a balance tank higher than the lowest water level in the tower water heat exchanger. (Refer to Figures 8, 9, and 10 in Appendix D., VII.)

In this application, the Isolation System shall begin at the normally closed tower water supply stop "block" valve and ends at the check-valve in the line returning to the open cooling tower.

Isolation is accomplished by meeting all of the following:

i) Closing the tower water supply valve. This tower water supply valve shall be a normally closed (spring-to-close) valve;

ii) Opening a full port vent valve on the supply side of the tower water heat exchanger and a full port drain valve prior to a check-valve in the tower water return line. This drain valve shall be normally open (spring-to-open);

iii) The drain valve and any pipes or pumps located between the drain valve and the heat exchanger must be lower than the lowest liquid level in the heat exchanger;

iv) De-energize any dedicated tower water supply pump, if present, located between the tower water reservoir and the tower water heat exchanger; and

v) If a tower water return pump is used, a bypass line may be used to flood the dry pump at start up.

(2) In a system with the overflow of an atmospheric balance tank lower than the lowest water level in the heat exchanger. (Refer to Figures 11 and 12 in Appendix D., VII.)

In this application, the Isolation System shall begin at the tower water balance tank and end at the check-valve in the line returning to the open cooling tower. Isolation is accomplished by meeting all of the following:

i) De-energizing the "local tower water supply pump", if present. (Refer to Figure 11 in Appendix D., VII.);

ii) Opening a full port vent valve on the supply side of the tower water heat exchanger;

iii) Open a full port drain valve prior to a check-valve in the tower water return line. This drain valve must be normally open (spring-to-open); and

iv) The drain valve and any pipes or pumps located between it and the heat exchanger must be lower than the lowest liquid level in the heat exchanger.

(3) Variations from the above Isolation Systems may be individually evaluated and found to also be acceptable by the Regulatory Agency, if the level of protection required by this ADMINISTRATIVE PROCEDURE is not compromised.

TESTING: A means to test the response of this Isolation System must be developed and available at the milk plant. The accuracy of the required differential pressure controller shall be checked by the Regulatory Agency on installation; every six (6) months thereafter; and following repair or replacement.

*** **NOTE:** Nothing shall be construed as barring other time and temperature relationships, which have been recognized by FDA to be equally efficient and which are approved by the Regulatory Agency.

Name:	Dr. Larry Steenson, Dr. Jan Payne, Beth Jones & Bart Van Belleghem		
Agency/Organization:	Danisco, Purac, Kerry Ingredients & Bienca		
Address:	201 New Century Parkway,11 Barclay Blvd, 3400 Millington Road,		
City/State/Zip:	New Century, KS; Lincolnshire, IL;Beloit, WS; Brussels, Belgium		
Telephone No.:	800-255-6837,847-634-6330, 680-363-3154,32-67-79-4465	E-mail Address:	Larry.steenson@danisco.com; j.payne@purac.com;beth.jones@kerry.com;bart.van.belleghem@bienca.com

Effect of Cooling Rate on Pathogen Survival in Cottage Cheese

Kathleen Glass, Lindsey McDonnell and Sandra Olson

Food Research Institute, UW-Madison
1550 Linden Drive, Madison, WI 53706
Contact: kglass@wisc.edu; 608.263.6935

Abstract: The effect of cooling rate of cold-filled cottage cheese on the potential for growth of post-processing contaminants *Listeria monocytogenes* was compared., Full-fat (FF, 4% fat) and reduced-fat (RF, 1% fat) cottage cheese were formulated with 55% dry curd and 45% cream dressing supplemented with microbial inhibitors which could be classified as "natural" but demonstrate antimicrobial activity. The pH of the product was adjusted to target pH 5.2 (measured on blended sample at 0-time). Treatments included:

1. Control – No Microbial Inhibitors, PMO Cooling Requirements(used for comparison purposes with inhibitors)
2. Control – No Microbial Inhibitors, Industry Cooling Requirements (not used for comparison purposes with inhibitors)
3. Inhibitor I – 0.04% Bioactive Protein I
4. Inhibitor I – 0.03% Bioactive Protein I
5. Inhibitor D – 0.15% Fermentate D
6. Inhibitor E – 0.1% Fermentate E
7. Inhibitor E – 0.1% Fermentate E + Live Culture
8. Inhibitor A – 0.5% Fermentate A
9. Inhibitor A – 0.3% Fermentate A

Inoculated products were cooled from 55°F to 45°F according to industry practices (within 72 hours), with the Control inoculated and maintained at 45°F, representing the National Conference on Interstate Milk Shipments (NCIMS) Pasteurized Milk Ordinance (PMO) requirements for cottage cheese.

Listerial populations increased 1.4 and 1.7-log CFU/g in the Control RF and FF cottage cheese stored, respectively, at 168 h (7 days), but not at 96 hours (4 days). In contrast, all the inhibitors evaluated either delayed or prevented growth of *L. monocytogenes* compared with the respective controls without inhibitors during the two-week trial. This study demonstrated that cottage cheese with initial pH 5.2 and containing certain natural microbial inhibitors will delay or prevent the growth of *L. monocytogenes* during slow cooling from 55 to 45°F in 72 hours, followed by storage at 45°F. Data from these trials confirm previous findings that the safety of cottage cheese without inhibitors is dependent on preventing the recontamination of this pasteurized product regardless of filling at 45°F or 55°F. Strict adherence to good manufacturing practices and good environmental monitoring program is essential to prevent recontamination of cottage cheese and to ensure safety.

Introduction:
As with all cultured dairy products, the safety of cottage cheese is primarily dependent on the use of pasteurized milk to eliminate vegetative bacterial pathogens and spoilage microorganisms, good manufacturing practices and sanitary operating procedures to reduce the potential for recontamination, and active fermentation with microbial cultures to compete with any pathogens should recontamination occur. Published data demonstrates that cooking curd to >50°C (122°F) before the addition of cream dressing will destroy any vegetative pathogens (such as *Listeria monocytogenes*, *Staphylococcus aureus*, and *Escherichia coli* O157:H7) and most spoilage microorganisms that may inadvertently enter the system (Arocha et al., 1992; Ehlers et a., 1982; Hudson et al., 1997; McDonough et al., 1967; Michelson et al., 1963; Ryser et al., 1985; Vecchionacce et al., 1978). A combination of relatively low pH and controlled temperatures will prevent outgrowth of any surviving spores of other bacterial pathogens, such as *Clostridium sporogenes* or *Bacillus cereus* during subsequent extended cooling and refrigerated storage, with sorbate providing an additional hurdle to growth (Chen and Hotchkiss, 1993; ICMSF, 1996). Earlier trials conducted at the Food Research Institute, UW-Madison, verified that *Bacillus cereus* and *Salmonella* will not grow in cottage cheese with pH $\leq$5.35 if cooled according to industry practices from 55 to 45°F over 72 hours (Glass et al., 2005, unpublished data; reports submitted to IDFA/MIF and FDA). *E. coli* O157:H7 did not grow in cottage cheese with pH 5.1 or pH 5.2 with 0.06% potassium sorbate, regardless if cooled according to PMO rate. (Glass et al., 2006, unpublished data; reports submitted to IDFA/MIF and FDA)

The objective of this study was to compare the effect of cooling rate on survival of *L. monocytogenes* in cottage cheese formulated with different microbial inhibitors derived from natural sources. This study was designed to determine equivalency in safety for industry versus PMO-required cooling rates. The ultimate goal was to determine whether industry filling and cooling temperatures and rates could match or reduce microbial growth compared with PMO cottage cheese temperature filling and storage temperatures if the cottage cheese was recontaminated with vegetative pathogens. Specifically, the effect of cooling rate was compared if contaminated cottage cheese were immediately chilled to 45°F or less (current PMO requirement) upon filling versus industry cooling from approximately 55 to 45°F over 72 hours for products with pH 5.2 and supplemented with "natural" microbial inhibitors.

Material and Methods:
Test Products: Cottage cheese used in this study was produced under good manufacturing conditions in a state inspected and NCIMS-listed dairy manufacturing facility and represented "generic" formulations at the maximum pH values for production. Cream dressing and dry curd were transported under refrigeration to the Food Research Institute, UW-Madison and stored at 4°C until recombination and use.

Ingredients for the full-fat and reduced-fat Control products without inhibitors included:

- Lowfat Cottage Cheese (1% fat): Grade A cultured nonfat milk, cream, nonfat milk, salt, guar gum, mono & diglycerides, carrageenan, locust bean gum, polysorbate 80, natural and artificial flavor, enzymes, vitamin A palmitate.

- Cottage Cheese (4% fat): Grade A cultured nonfat milk, cream, reduced minerals whey, salt, nonfat milk, guar gum, mono & diglycerides, carrageenan, locust bean gum, polysorbate 80, natural and artificial flavor, enzymes.

Analytical values for the curd, cream dressings and finished Control cottage cheese were assayed as described in Table 1.

General Make Procedure:
Curd: Raw milk was separated into skim milk and pasteurized. Pasteurized skim milk was cultured with a commonly used industry starter culture consisting of a mix of mesophilic and thermophilic cultures (Chr. Hansen, F-DVS-FRESCO 1000-10) and microbial rennet added to the vat during the filling. The vat was allowed to incubate at 89°F for approximately 4.5 hours until the desired consistency of the coagulum and pH of 4.60 was achieved. At that point the coagulum was cut, acidified to pH 4.55 with phosphoric acid to stop culture growth, and the curd was allowed to heal. The whey was heated through tubular heat exchangers and some was added back into the curd vat to "cook" the curd at a temperature of 130°F. The curd and whey were pumped from the vat and separated through a belt drainer. After the belt drainer, the curd was mixed with chilled water (55°F) and sent to washers to rinse the whey from the curd. The curd and water mixture was pumped from the washers to another drainer and run through a pressurized belt to insure the curd Total Solids were 18.5%. Curd was dispensed into 5-gallon plastic pails with lids, which were thoroughly clean, sanitized and rinsed, for transport. A single batch of curd was used for all the *L. monocytogenes* experiments

Cream Dressing: Milk and cream stored at 38°F were blended together in a tank. Stabilizers, flavor, nonfat dry milk and salt (and vitamin A for low-fat cottage cheese) were added through a Liquifier blender. This mixture was then pasteurized at 188-190°F and cooled to 38°F before being dispensed into 5-gallon plastic pails with lids, which were thoroughly clean, sanitized and rinsed, for transport. Two batches of cream dressing, full-fat and reduced-fat, were used for the *L. monocytogenes* experiments.

Treatments: Treatments included (percentages listed are w/w finished product):
1. Control – No Antimicrobials
2. Inhibitor I – 0.04% Bioactive Protein I (added after pasteurization and immediate prior to inoculation)
3. Inhibitor I – 0.03% Bioactive Protein I (diluted from Treatment 0.04% Bioactive Protein I)
4. Inhibitor D – 0.15% Fermentate D (added before re-pasteurization)
5. Inhibitor E – 0.1% Fermentate E (added before re-pasteurization)
6. Inhibitor E – 0.1% Fermentate E (same as Treatment 0.1% Fermentate E) + live culture (added after pasteurization and immediate prior to inoculation)
7. Inhibitor A – 0.5% Fermentate A (added before re-pasteurization)
8. Inhibitor A – 0.3% Fermentate A (diluted from Treatment 0.5% Fermentate A)

Proposed label statements for natural ingredients with antimicrobial activity:
Inhibitor I: exempt from labeling in cottage cheese; classified as an incidental additive by the US Food and Drug Administration and as a processing aid by CODEX Alimentarius (FAO/WHO)

Inhibitor D: Cultured Skim Milk
Inhibitor E: (Fermentate) Cultured Grade "A" Skim Milk and Nonfat Dry Milk. Certified Kosher Dairy. Certified Halal OR Cultured Corn Syrup Solids. Certified Kosher Pareve. Certified Halal. (Live culture) Starter Cultures. Certified Kosher Dairy and Halal.
Inhibitor A: Cultured dairy solids, calcium lactate

Repasteurization of Cream Dressing and Laboratory Preparation: Curd and two types of cream dressing (full-fat and reduced-fat) were transported in a refrigerated truck to UW-Madison within 12 hours of preparation and stored at 4°C until use. The two fat levels of cream dressings were divided for the various treatments. Each batch was pasteurized in a covered 35 L capacity steam-jacketed Stephan cooker to a minimum 160°F (72°C) with continuous slow agitation for 30 minutes, cooled to 40°F (4°C) within 30 minutes, and dispense into 5 gallon pails. Batch pasteurization was completed at the Babcock Hall Pilot Plant, UW-Madison, and cream dressings transported to the nearby Food Research Institute building on the UW-Madison campus to mix with curd and for inoculation of the final cottage cheese product.

Portions of cream dressing were re-pasteurized without microbial inhibitor additions to provide control samples without inhibitors, portions to be used for dilution of inhibitors, and portions to which heat-sensitive Bioactive Protein I was added. For Treatments D, E, and A, antimicrobial ingredients (0.15% Fermentate D; 0.1% Fermentate E; and 0.5% Fermentate A) were first added to individual portions of cream dressing, blended using a portable mixer until homogeneous, and then re-pasteurized. All cream dressings were stored at 4°C and used within 24 hours of re-pasteurization.

Immediately prior to mixing with curd and inoculation, Treatment A (0.5% Fermentate) were then further subdivided and one portion diluted with control cream dressing to yield the appropriate lower concentration of inhibitor (A - 0.3%); live starter culture E was added to a sub-portion of Treatment E (no dilution) immediately prior to mixing with the curd and inoculation. In addition, Treatment I at both concentrations (0.04% and 0.03% Bioactive Protein I) were added to the cream dressing after pasteurization and immediately prior to mixing with the curd and inoculation.

Prior to inoculation for each treatment, cream dressing and curd were individually measured into sterilized beakers, and tempered in an incubator set to 55°F for 1 hour. The appropriate volume of 5 N NaOH was added to the cream dressing such that the pH of the blended finished product was 5.20-5.25 (see description below). For each batch, 55% curd and 45% of the appropriate dressing (without or with inhibitors) were mixed by hand for 5 minutes in sterile 10 L capacity polypropylene trays using large sterile stainless steel spoons.

Uninoculated samples were dispensed into 120 ml capacity polyethylene sample vials, capped, and cooled immediately to 45°F (PMO) by place on ice for several minutes or cooled from 55°F in 72 hours per industry cooling curve (Industry). The remaining cottage cheese was inoculated as described below and similarly dispensed and stored according to one of the two cooling regimes.

K. Glass, Food Research Institute, UW-Madison
608.263.6935; kglass@wisc.edu

pH adjustment and measurement: The pH of the cottage cheese was adjusted by determining the volume of 5 M NaOH required to increase the pH to 5.20-5.25 for blended samples. NaOH was added to representative 500 g batches for each treatment, samples homogenized, and the pH determined on samples at 18-22°C using a calibrated Orion combination electrode and Accumet pH meter. Volumes were multiplied for 6000 g final batches. Blended samples represented cottage cheese after full equilibration (typically 2-3 days). The pH of the samples at each sampling interval were measured on "as is" (unblended) cottage cheese, and varied depending on proportion of cream dressing in each sample cup and the number of days storage.

Table 1. Proximate analysis and analytical methods for curd, dressing and finished full-fat and low-fat Control cottage cheese (analytical values reported are averages of triplicate uninoculated samples)

	Full-fat Cottage Cheese	Low-fat Cottage Cheese	Analytical Method
% Moisture - Curd	81.64	Same as FF Treatment	5 h, vacuum oven method, 100°C; Marshall, 1992
% Moisture - Dressing	77.36	82.94	
% Moisture Finished Control Cottage Cheese	79.59	81.64	
pH - Curd	4.66	Same as FF Treatment	Direct pH; Accumet pH meter and Orion 8160 combination Electrode; pH meter/electrode was calibrated daily per manufacturer's procedures using commercially prepared pH 4.0 and 7.0 standard buffers. Samples warmed to ~20°C before pH measurement
pH - Dressing	6.30	6.30	
pH Finished Control Cottage Cheese (w/out adjustment)	5.20	5.22	
% Titratable Acidity Curd	1.22%	Same as FF Treatment	Expressed as % lactic acid; use 9-10 g sample; Metter automatic titration using 0.1N NaOH to pH 8.1
% Titratable Acidity Dressing	0.13%	0.16%	
% Titratable Acidity Finished Control Cottage Cheese	0.46%	0.50%	
% NaCl - Curd	<0.05	Same as FF Treatment	Measured as % Cl^-; $AgNO_3$ titration, Mettler automatic titration; standards at 1, 1.5 and 2.0% NaCl solutions run each day
% NaCl - Dressing	2.48%	2.53%	
% NaCl Finished Control Cottage Cheese	1.17%	1.17%	
Water Activity - Curd	0.996 @ 25.0°C	Same as FF Treatment	Decagon CX-2 Water activity meter; calibrated per manufacturer's specifications
Water Activity - Dressing	0.973 @ 25.0°C	0.976 @ 25.0°C	
Water Activity Finished Control Cottage Cheese	0.982 @ 24.8°C	0.982 @ 25.3°C	
Fat	4.4%	1.3%	Calculated from formulation data; Not analyzed by FRI
Protein	10.6%	11.5%	Calculated from formulation data; Not analyzed by FRI

Inoculum:

Table 2. Strains of *L. monocytogenes* used to inoculate cottage cheese.

Strain designation	*Source*
FSL R2-501	Human isolate associated with NC soft-Hispanic style cheese outbreak[1]
FSL R2-500	Soft-Hispanic style cheese isolate associated with NC outbreak[1]
LM101	Hard salami isolate[2]
LM310	Goat cheese isolate associated with human spontaneous abortion[2]

Strains from FRI stocks (previously frozen in 10% glycerol at -20°C; see table above for source of strains) were initially grown in Trypticase soy broth (TSB; incubated at 37°C, 18-20 hours). Strains were confirmed for purity by streaking on non-selective and Modified Oxford agar (MOX, 35°C, 48 h)). Select colonies were confirmed using the appropriate Micro-ID (Remel) miniaturized biochemical identification system.

Strains of *L. monocytogenes* were grown individually to stationary phase in TSB supplemented with 1% glucose to induce acid-tolerance (incubated at 35°C for 18 hours, two successive transfers), harvested by centrifugation at 2,500 X g for 20 minutes and washed with 0.1% buffered peptone water (BPW). Strains were mixed in approximately equal concentrations and the inocula diluted in BPW to deliver approximately 3.5-log CFU/g cottage cheese. Populations of the four-strain mixture and of individual strains were verified by plating serial dilutions on MOX. Each strain was also verified for purity by streaking on nonselective Trypticase Soy Agar (TSA, 35°C, 24 h).

Inoculation, packaging, and storage:

For each product type, 2,700 g cream dressing and 3,000 g curd (ratio 45% dressing:55%curd; tempered to 50-55°F) was mixed in a sterilized Nalgene® polypropylene tray. After removing uninoculated samples for microbial and proximate analysis and for temperature blanks, product was inoculated with 6 ml of pathogen mixture by dripping inoculum over the surface and gently hand-stirring for approximately 5 minutes. Inoculated cottage cheese was dispensed into 120 g capacity sample vials (approximately 100 g/cup; 0.25" headspace maximum) and capped. The internal temperature for each product type was monitored with a thermocouple[3] (type K probe) inserted into one cup for each cooling scenario.

After inoculation and filling, packages were then divided for different storage temperatures to represent current PMO requirement (45°F) or industry cooling procedures. The target "typical 72 h" exponential industry cooling curve was developed by CFSAN from data supplied by the Milk Industry Foundation for a representative variety of product sizes and cooling rates. For PMO-required cooling treatment, samples were chilled on ice for approximately 10-15 minutes until

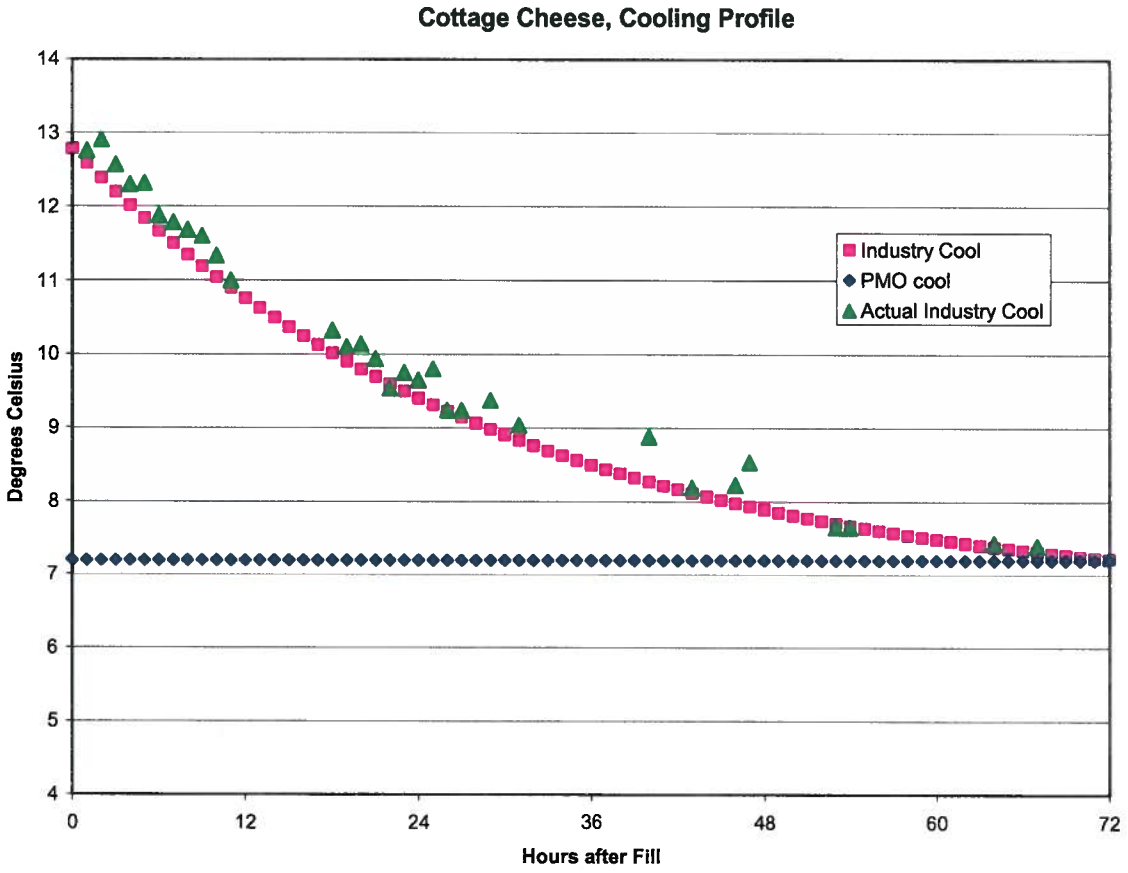
[1] ILSI North America Listeria Collection, Cornell University

[2] FRI Listeria Collection, UW-Madison

[3] Thermocouples were calibrated against a factory-calibrated mercury-filled thermometer (FisherBrand, factory-calibrated to meet the requirements of ISO/EC Guide 25, ANSI/NCSL 2540-1-1994, ISO 9000/QS 9000 Series of Quality Standards, and MIL STD 45662A).

product temperature was ≤45°F, and then transferred to an incubator with air temperature set to 45°F. For the industry-cooling treatment, samples were transferred to a programmable incubator with air temperature set to 55°F and the air temperature adjusted hourly to mimic the designated industry-cooling regime (Figure 1). Temperatures were recorded in degrees Celsius and converted to degrees Fahrenheit for this report.

Figure 1. Temperature profile for cottage cheese chilled to 7.2°C (45°F) in 30 minutes (PMO) or cooled from 12.8°C (55°F) to 7.2°C in 72 hours and stored at 7.2°C for 14 days. Actual Industry Cool data average of two-three samples for two programmable incubators (n=4 to 6). Samples were rotated within the incubator every 8 to 12 hours ensure similar cooling opportunities.



Pathogen Enumeration: For each treatment, triplicate samples were enumerated for populations of *L. monocytogenes* at 0-time (within 30 minutes of inoculation), 24, 48, 72, 96, 168, 240, and 336 hours (days 0, 1, 2, 3, 4, 7, 10, and 14). Samples were assayed by aseptically removing a 25-g sample, diluting with an equal volume (w/v) buffered peptone water (BPW) and thoroughly homogenizing using a Lab Blender Stomacher Model 400 (Cooke Laboratory Products, Alexandria, VA). Serial dilutions were made in BPW and 0.1 ml aliquots surface-inoculated onto duplicate plates of MOX. Plates were incubated at 35°C (95°F) for 48 h. The appearance

of typical colonies on selective agar was considered confirmatory. Atypical colonies (such as micro colonies) were counted separately and confirmed as appropriate to include in the final calculations for plate counts.

Uninoculated Product: Proximate analyses included pH, moisture, salt, and water activity, measured for curd and each dressing type on duplicate uninoculated samples at 0-time (Note: milkfat and protein levels were determined by nutritional labeling). The pH was determined directly with an Accumet pH meter and an Orion (or other comparable) combination pH electrode on a blended sample for pH adjustment and on unblended samples for each subsequent sampling interval (pH measured at room temperature). Moisture was measured by the vacuum oven method (5 h, 100°C, vacuum oven method). Water activity (a_w) was determined with a CX-2 water activity meter (Decagon Devices, Pullman, WA). The aerobic plate count (Plate count agar, 25°C, 72 hours) and titratable acidity of the cream dressing was measured after re-pasteurization, of the curd upon receipt at the laboratory, of the finished mixture immediately prior to pathogen inoculation at the laboratory, and at the end of the 14-day testing interval. In addition, to 1:1 diluted samples were plated on MacConkey sorbitol agar (MSA) as a screen for potential Gram-negative contamination. No confirmation was completed for colonies observed.

Results and Discussion:

Changes in populations of *L. monocytogenes:* Data for changes in microbial populations are reported in Tables 3-10 and Figures 2-5. All inhibitors tested in cottage cheese cooled according to the Industry curve provided either similar growth rate or greater control of *L. monocytogenes* than PMO Control product without inhibitors and stored at 45°C.

When inoculated RF and FF **Control** cottage cheese was cooled to 45°F according to PMO requirements, populations of *L. monocytogenes* increased 1.4 and 1.7-log CFU/g, respectively, at 168 h (7 days), but no significant growth was detected at 96 hours (4 days). *L. monocytogenes* grew 1-log CFU/g at 72 hours for both FF and RF Controls without microbial inhibitors using the industry cooling curve (starting at 55°F and cooling to 45°F at the end of 72 hours). All Controls, using either the PMO-mandated cooling requirements (45°F) or the industry cooling curve supported an approximately 5-log increase of *L. monocytogenes* at Day 14, regardless of cooling rate (Table 3).

Inhibitor I (Bioactive Protein) used at the 0.04% level prevented growth of *L. monocytogenes* at 10 days in both RF and FF products using Industry cooling practices, compared with a 1.4 and 1.7 log increase at Day-7, respectively in PMO-cooled Control products without inhibitors. At Day-14, cottage cheese supplemented with 0.04% Inhibitor I supported a 0.9 and 2.8 log increase for RF and FF Industry Cool, respectively, compared with 4.8 to 5.0 log increase in PMO-cooled Control products. Use of 0.03% Inhibitor I similarly delayed growth under Industry cooling conditions with 0.8 and 2.3 log increase at Day-10 versus a 3.1 and 3.8 log increase in the PMO-cooled Control product. At Day-14, there was a 2.4 and 3.4 log increase for RF and FF products, respectively while the PMO-cooled Control product had a larger 4.7 and 4.9 log increase. The industry cooling along with microbial inhibitor I at either the 0.3% or 0.4% level

prevents *L. monocytogenes* growth through Day 7 and inhibits growth to a level approximately 2 logs less than the PMO-cooled Control product at Days10 and 14. (Tables 3-5 and Figure 2).

Inhibitor D (Fermentate) used at 0.15% resulted in less than a 1-log increase up to Day-10 for the RF product and a 1.4 log increase at Day-10 for the FF product compared with the PMO-cooled Control that allowed a 3 log growth for RF and a 3.8 log growth for FF product. At Day-14, 0.15% Inhibitor D used in Industry-cooled samples showed 3.0-3.9 log increase in *L. monocytogenes* for the RF and FF product, respectively, compared with 4.7-5.0 for Control-PMO treatments. At 14 days, the 0.15% concentration of Inhibitor D with the industry cooling had an approximately 1 log lower growth level than the PMO-cooled product for both fat levels. (Tables 3, 6 and Figure 3)

Inhibitor E (Fermentate) used at a concentration of 0.1% in cottage cheese cooled according to Industry practices likewise inhibited listerial growth to <1 log increase until Day-7; listerial population growth was approximately 0.5 logs below the D-7 values for FF and equivalent to the RF Control-PMO treatment which supported 1.4 to 1.7 log at the same testing interval. At 14-days, populations of *L. monocytogenes* in cottage cheese supplemented with 0.1% Fermentate E and cooled per Industry practices increased only 2.7-log CFU/g compared with a 4.7 – 4.9 log increase for Control-PMO treatment, a 2 log difference for product with the inhibitor and the industry cooling. When cottage cheese was supplemented with 0.1% **Inhibitor E Fermentate plus Live Culture**, growth of *L. monocytogenes* was prevented (<0.3 log increase) under Industry cooling for the entire 14-day study for FF products, with only a 0.6 log increase for RF product, compared with the 5-log increase in *L. monocytogenes* populations for the Control-PMO treatments at the same sampling interval (Tables 3, 7, 8, and Figure 4).

Inhibitor A (Fermentate) with the industry cooling consistently prevented growth of *L. monocytogenes* in cottage cheese throughout the 14-day study for both fat levels when used at the 0.5% level, demonstrating no growth in the RF product at the 0.3% level and only a 0.7% increase in the FF product. In contrast, populations of *L. monocytogenes* for the PMO-cooled product without any inhibitor increased at a minimum of 1.4, 3 ,and 5-log CFU/g at 7, 10, 14 days, respectively regardless of cottage cheese fat level (Tables 3, 9, 10, and Figure 5).

Changes in titratable acidity, pH, and populations of spoilage microorganisms:
The pH values of "as is" samples were approximately 0.05 to 0.15 higher than representative blended samples at 0-time. The differences in pH values may be attributed to delay in pH equilibration between the curd (pH ~4.7) and the cream dressing (pH ~6.3). Variation in pH values during the 14-day testing interval was minimal, demonstrating very little lactic bacteria activity likely to produce lactic acid and reduce pH. (Tables 3-10).

Percent titratable acidity (expressed as % lactic acid) remained relatively unchanged for all treatments throughout the 14-day testing interval, 0.63±0.05% with an average increase of 0.08% from D-0 to D-14 (individual data not shown).

Aerobic plate (APC) counts at 0-time were an average 2.28±0.48 log CFU/g for all treatments, except for Inhibitor E Fermentate with Live Culture treatment, which had 6.99±0.13 log CFU/g

due to the addition of live culture after pasteurization of the dressing. At the end of the 14-day testing interval, average APC increased an average 4 to 5 log CFU/g for Control, either Inhibitors D and I, and Inhibitor E Fermentate only. APC increased an average 2.0 and 3.0 log CFU/g for Inhibitor A at 0.5 and 0.3%, respectively. Populations for uninoculated Treatment E with Live Culture increased approximately 0.5 log CFU/g during storage. Rate of cooling had no consistent effect on growth of spoilage microorganisms between comparable formulations (individual data not shown).

For 0-time uninoculated samples, individual colonies were rarely recovered on MSA (theoretical detection limit <1 log CFU/g). At the 14-day sampling interval, microbial populations recovered on MSA increased to 1-3 log CFU/g for all uninoculated Control samples without inhibitors, but no consistent trend was associated with cooling rate. Sporadic growth of Gram-negative spoilage microorganisms was noted in uninoculated samples with inhibitors. No isolates were recovered for samples supplemented with Inhibitors A and E. For Inhibitor D and I >4-log CFU/g were observed in sporadic samples, whereas no colonies (theoretical detection limit 1.0-log CFU/g) were observed from most samples from the same treatments. No consistent trends were observed for recovery of colonies from MSA among the various treatments and observation of apparent growth was likely associated with sporadic contamination at 0-time.

Most samples appeared to be normal in odor and appearance; no obvious mold growth or gross spoilage was noted (individual data not shown).

Conclusion:

Data from this study demonstrated that all seven (7) microbioal inhibitors used in this challenge study provide similar or greater inhibition of *L. monocytogenes* growth in cottage cheese with the industry cooling regime (filling at 55°F and cooling the product down to 45°F within 72 hours) compared with cottage cheese without inhibitors and filled and cooled according to the current regulatory requirement (filling at 45°F and maintaining the product at 45°F during storage and distribution).

Even though the food safety history of cottage cheese in the U.S. is very good, the use of these microbial inhibitors at the concentrations identified in this challenge study (or greater) will increase the level of safety for this product. It must also be acknowledge that industry practices during the processing of cottage cheese, e.g. the use of hygienically designed and properly maintained and cleaned processing equipment, operational good manufacturing programs (GMPs) and well-training employees, play a critical role in producing a safe cottage cheese product.

References:

1. Arocha, M.M., M. McVey, S.D.Loder, J.H. Rupnow, and L. Bullerman. 1992. Behavior of hemorrhagic *Escherichia coli* O157:H7 during the manufacture of cottage cheese. J. Food Prot. 55:379-381.

2. Chen, J.H., and J.H. Hotchkiss. 1993. Growth of *Listeria monocytogenes* and *Clostridium sporogenes* in cottage cheese in modified atmosphere packaging. J. Dairy Sci. 76:972-977.

3. Ehlers. J.G., M. Chapparo-Serrano, R. Richter, and C. Vanderzant. 1982. Survival of *Campylobacter fetus* subsp. *jejuni* in Cheddar and cottage cheese. J. Food Prot. 45:1018-1021.

4. Gonzalez, I., M. Lopez, S. Martinez, A. Bernardo, and J. Gonzelez. 1999. Thermal inactivation of Bacillus cereus spores formed at different temperatures. Int. J. Food Microbiol. 51:81-84

5. Hudson, L.M., J. Chen, A.R. Hill, and M.W. Griffiths. 1997. Bioluminescence: a rapid indicator of Escherichia coli O157:H7 in selected yogurt and cheese varieties. J. Food Prot. 60:891-897.

6. International Commission on the Microbiological Specifications of Foods. 1996. Microorganisms in Foods: 5 Microbiological Specifications of Food Pathogens. Blackie Academic and Professional. An Imprint of Chapman and Hall, London.

7. Marshall, R.T. 1992. Standard methods for the examination of dairy products. 16th ed. American Public Health Association, Washington, DC.

8. McDonough, F. E., R. E. Hargrove, and R. P. Tittsler. 1967. The fate of *Salmonella* in the manufacture of cottage cheese. J. Milk Food Technol. 30:354-356.

9. Michelson, R., V.D. Foltz, W.H. Martin, and C.A. Hunter. 1983. Staphylococci in cottage cheese. J. Milk food Technol. 26:74-77.

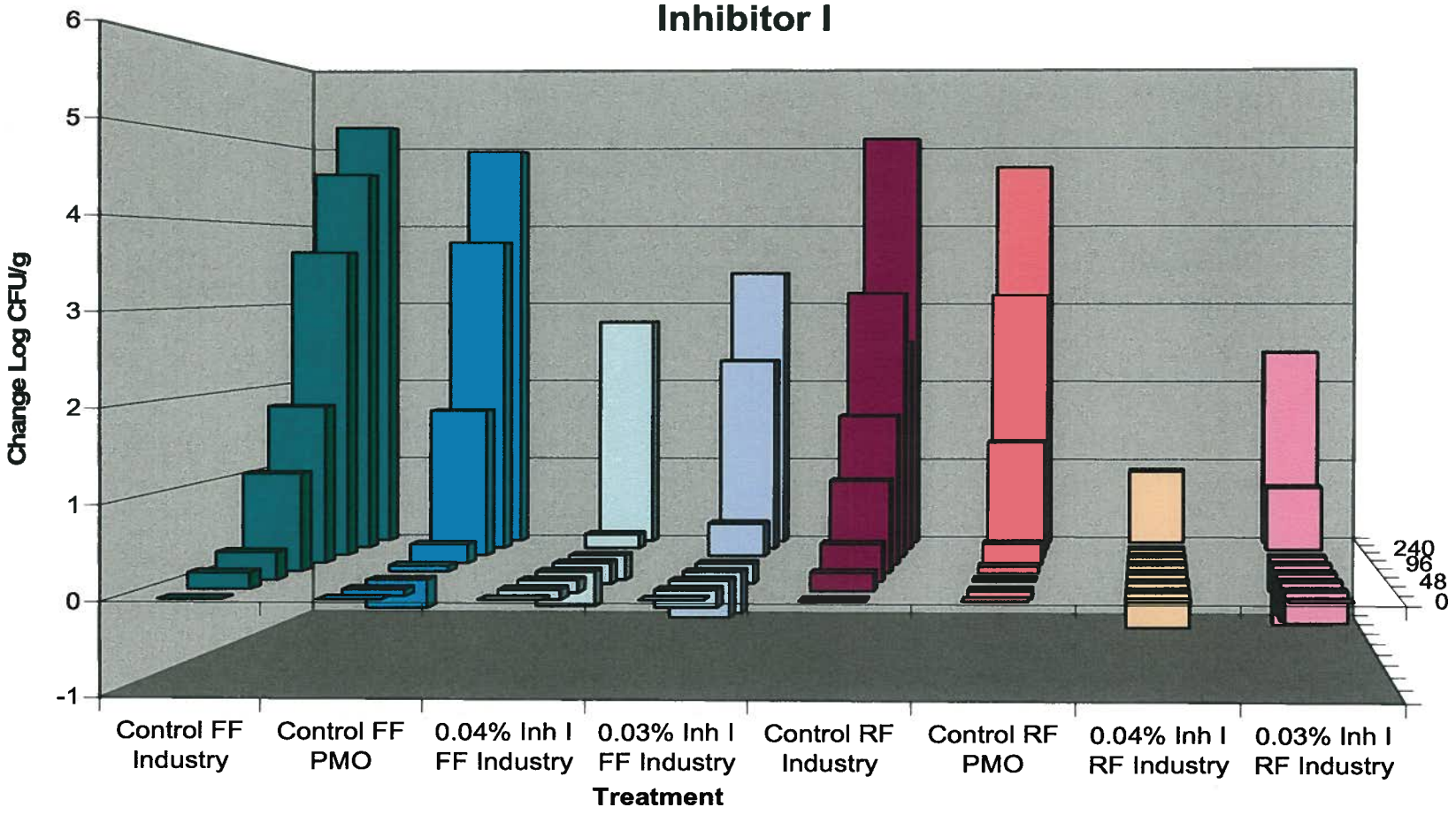
10. Ryser,-E.T.; Marth,-E.H.; Doyle,-M.P. 1985. Survival of *Listeria monocytogenes* during manufacture and storage of Cottage cheese. J-Food-Prot. 48:746-750, 753.

11. United States Food and Drug Administration. Bacteriological analytical manual Online. 2001. Hypertext Source: Bacteriological Analytical Manual, 8th Edition, Revision A, 1998. Chapter 14. *Authors: E. Jeffery Rhodehamel and Stanley M. Harmon Contacts: Negosh Belay, D. B. Shah and Reginald Bennett. AOAC International, Washington, DC. http://www.cfsan.fda.gov/~ebam/bam-14.html

12. Vecchionacce,-R-A; Bassette,-R; Metha,-R-S. 1978. Survival of *Escherichia coli,* strain W, during the manufacture of Cottage cheese. J. Dairy-Sci 61: 1704-1708

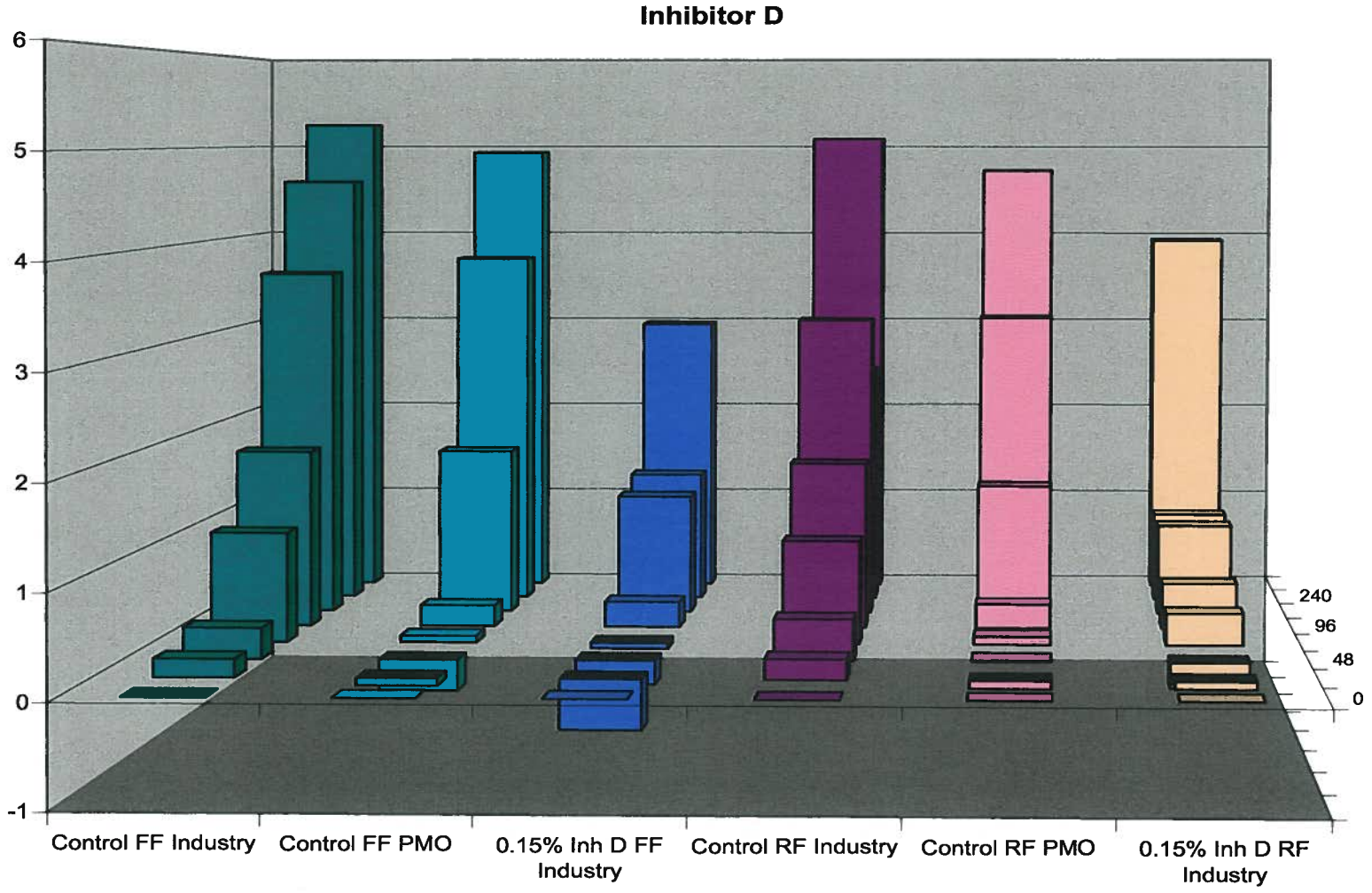
K. Glass, Food Research Institute, UW-Madison
608.263.6935; kglass@wisc.edu

Figure 2. Antilisterial effect of **Inhibitor I** in full-fat (FF) and reduced-fat (RF) cottage cheese filled at 55°F and cooled to 45°F within 72 hours (Industry Cool) compared with Control Cottage Cheese without inhibitor and Industry Cool and PMO Cool (45°F) without inhibitor.



K. Glass, Food Research Institute, UW-Madison
608.263.6935; kglass@wisc.edu

Figure 3. Antilisterial effect of **Inhibitor D** in full-fat (FF) and reduced-fat (RF) cottage cheese filled at 55°F and cooled to 45°F within 72 hours (Industry Cool) compared with Control Cottage Cheese without inhibitor and Industry Cool and PMO Cool (45°F) without inhibitor.



K. Glass, Food Research Institute, UW-Madison
608.263.6935; kglass@wisc.edu

Figure 4. Antilisterial effect of **Inhibitor E Fermentate (F only)** and **Inhibitor E + Live Culture (F+C)** in full-fat (FF) and reduced-fat (RF) cottage cheese filled at 55°F and cooled to 45°F within 72 hours (Industry Cool) compared with Control Cottage Cheese without inhibitor and Industry Cool and PMO Cool (45°F) without inhibitor.

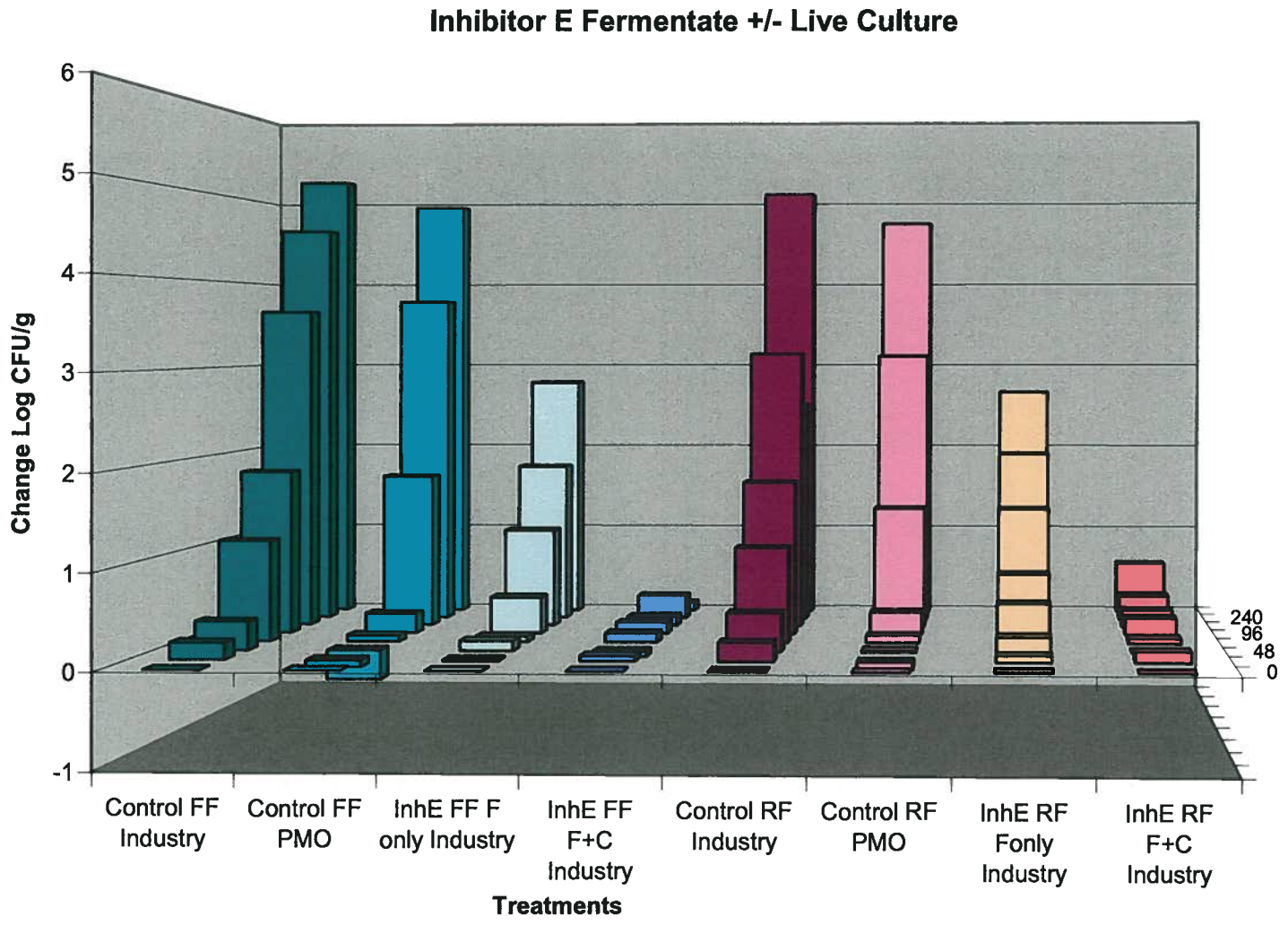
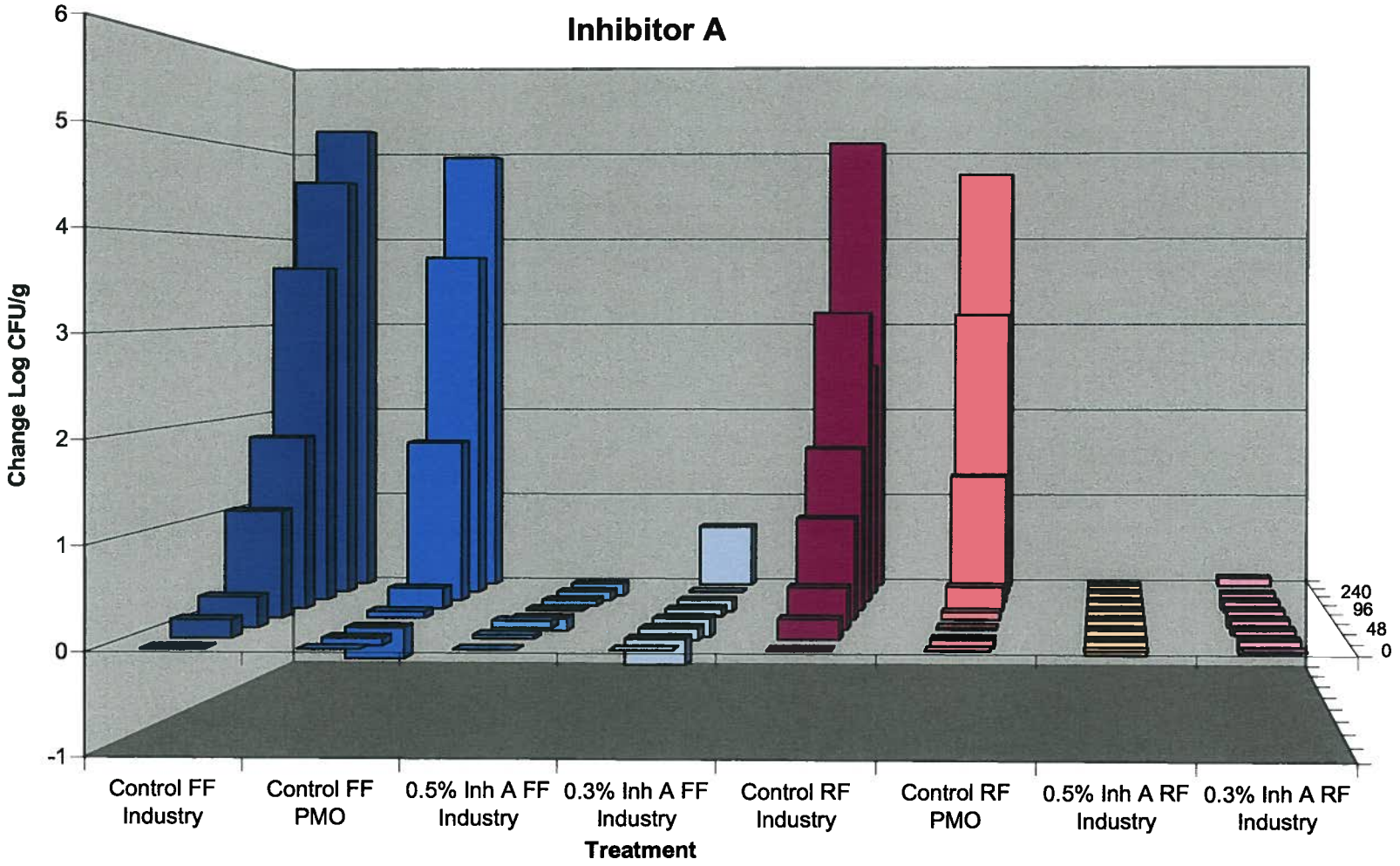


Figure 5. Antilisterial effect of **Inhibitor A** in full-fat (FF) and reduced-fat (RF) cottage cheese filled at 55°F and cooled to 45°F within 72 hours (Industry Cool) compared with Control Cottage Cheese without inhibitor and Industry Cool and PMO Cool (45°F) without inhibitor.



K. Glass, Food Research Institute, UW-Madison
608.263.6935; kglass@wisc.edu

Table 3. Changes in populations of *Listeria monocytogenes* (log CFU/g[1]) and pH[2] in full-fat (FF) and reduced-fat (RF) cottage cheese **Control without inhibitors** (blended 0-time FF pH 5.24; RF pH 5.28) filled at 55°F and cooled to 45°F within 30 minutes (PMO cool) or within 72 hours (Industry Cool).

Days after fill	Control FF PMO		Control FF Industry		Control RF PMO		Control RF Industry	
	L. monocytogenes Log CFU/g	*pH*	*L. monocytogenes* Log CFU/g	*pH*	*L. monocytogenes* Log CFU/g	*pH*	*L. monocytogenes* Log CFU/g	*pH*
0	3.41	*5.32*	3.41	*5.32*	3.37	*5.34*	3.37	*5.34*
1	3.34	*5.29*	3.58	*5.27*	3.29	*5.32*	3.56	*5.34*
2	3.10	*5.25*	3.71	*5.30*	3.38	*5.35*	3.78	*5.33*
3	3.47±0.36	*5.24*	4.51	*5.26±0.07*	3.44	*5.29*	4.41	*5.27*
4	3.62	*5.24*	5.23	*5.27*	3.62	*5.31*	5.08	*5.31*
7	5.13	*5.28*	7.05	*5.27*	4.73±0.36	*5.33*	6.52±0.31	*5.34*
10	7.17	*5.35*	8.02	*5.39*	6.49	*5.39*	5.91	*5.39*
14	8.34	*5.26*	8.65	*5.32*	8.09	*5.32*	8.45	*5.24*
Change from 0-time								
1	-0.07	*-0.03*	0.18	*-0.05*	-0.08	*-0.01*	0.20	*0.00*
2	-0.31	*-0.07*	0.31	*-0.02*	0.02	*0.01*	0.41	*0.00*
3	0.07	*-0.08*	1.11	*-0.06*	0.08	*-0.04*	1.04	*-0.07*
4	0.22	*-0.08*	1.82	*-0.05*	0.25	*-0.02*	1.71	*-0.02*
7	1.73	*-0.04*	3.64	*-0.05*	1.37	*-0.01*	3.15	*0.00*
10	3.77	*0.03*	4.61	*0.07*	3.12	*0.05*	2.54	*0.05*
14	4.93	*-0.06*	5.24	*0.00*	4.73	*-0.02*	5.09	*-0.10*

[1] Populations reported as log CFU/g for average of triplicate samples for each treatment and sampling interval; standard deviation ≤0.30 log unless reported otherwise

[2] pH values reported on "as is" (unblended) samples for average of triplicate samples for each treatment and sampling interval; standard deviation ≤0.05 pH units unless reported otherwise.

K. Glass, Food Research Institute, UW-Madison
608.263.6935; kglass@wisc.edu

Table 4. Changes in populations of *Listeria monocytogenes* (log CFU/g[1]) and pH[2] in full-fat (FF) and reduced-fat (RF) cottage cheese with **0.04% Inhibitor I** (blended 0-time FF pH 5.24; RF 5.30) filled at 55°F and cooled to 45°F within 30 minutes (PMO cool) or within 72 hours (Industry Cool).

Days after fill	**Control FF PMO**		**0.04% Inhibitor I FF Industry**		**Control RF PMO**		**0.04% Inhibitor I RF Industry**	
	L. monocytogenes Log CFU/g	*pH*	*L. monocytogenes* Log CFU/g	*pH*	*L. monocytogenes* Log CFU/g	*pH*	*L. monocytogenes* Log CFU/g	*pH*
0	3.41	*5.32*	3.29	*5.32*	3.37	*5.34*	3.38	*5.42*
1	3.34	*5.29*	3.18	*5.29*	3.29	*5.32*	2.99	*5.36*
2	3.10	*5.25*	3.15	*5.24*	3.38	*5.35*	3.01	*5.36*
3	3.47±0.36	*5.24*	2.89	*5.23*	3.44	*5.29*	2.83	*5.34*
4	3.62	*5.24*	3.04	*5.25*	3.62	*5.31*	3.17	*5.34*
7	5.13	*5.28*	2.99	*5.19*	4.73±0.36	*5.33*	2.75	*5.35*
10	7.17	*5.35*	3.45	*5.33*	6.49	*5.39*	3.12±0.45	*5.45*
14	8.34	*5.26*	6.05±0.53	*5.22*	8.09	*5.32*	4.27±0.86	*5.31*
Change from 0-time								
1	-0.07	*-0.03*	-0.10	*-0.03*	-0.08	*-0.01*	-0.39	*-0.06*
2	-0.31	*-0.07*	-0.14	*-0.08*	0.02	*0.01*	-0.37	*-0.06*
3	0.07	*-0.08*	-0.39	*-0.09*	0.08	*-0.04*	-0.55	*-0.08*
4	0.22	*-0.08*	-0.25	*-0.06*	0.25	*-0.02*	-0.21	*-0.09*
7	1.73	*-0.04*	-0.30	*-0.13*	1.37	*-0.01*	-0.63	*-0.07*
10	3.77	*0.03*	0.17	*0.02*	3.12	*0.05*	-0.25	*0.03*
14	4.93	*-0.06*	2.77	*-0.10*	4.73	*-0.02*	0.89	*-0.11*

[1] Populations reported as log CFU/g for average of triplicate samples for each treatment and sampling interval; standard deviation ≤0.30 log unless reported otherwise

[2] pH values reported on "as is" (unblended) samples for average of triplicate samples for each treatment and sampling interval; standard deviation ≤0.05 pH units unless reported otherwise.

K. Glass, Food Research Institute, UW-Madison
608.263.6935; kglass@wisc.edu

Table 5. Changes in populations of *Listeria monocytogenes* (log CFU/g[1]) and pH[2] in full-fat (FF) and reduced-fat (RF) cottage cheese with **0.03% Inhibitor I** (blended 0-time FF pH 5.24; RF 5.30) filled at 55°F and cooled to 45°F within 30 minutes (PMO cool) or within 72 hours (Industry Cool).

Days after fill	**Control FF PMO**		**0.03% Inhibitor I FF Industry**		**Control RF PMO**		**0.03% Inhibitor I RF Industry**	
	L. monocytogenes Log CFU/g	*pH*	*L. monocytogenes* Log CFU/g	*pH*	*L. monocytogenes* Log CFU/g	*pH*	*L. monocytogenes* Log CFU/g	*pH*
0	3.41	*5.32*	3.36	*5.33*	3.37	*5.34*	3.44	*5.40*
1	3.34	*5.29*	3.18	*5.27*	3.29	*5.32*	3.11	*5.36*
2	3.10	*5.25*	2.96	*5.25*	3.38	*5.35*	3.01	*5.32*
3	3.47±0.36	*5.24*	2.89	*5.24*	3.44	*5.29*	2.97	*5.35*
4	3.62	*5.24*	3.13	*5.24*	3.62	*5.31*	2.74	*5.32*
7	5.13	*5.28*	3.74	*5.24*	4.73±0.36	*5.33*	3.02	*5.34*
10	7.17	*5.35*	5.66	*5.28*	6.49	*5.39*	4.20±0.31	*5.40*
14	8.34	*5.26*	6.75±0.35	*5.25*	8.09	*5.32*	5.82±0.45	*5.30*
Change from 0-time								
1	-0.07	*-0.03*	-0.18	*-0.06*	-0.08	*-0.01*	-0.33	*-0.04*
2	-0.31	*-0.07*	-0.40	*-0.08*	0.02	*0.01*	-0.42	*-0.08*
3	0.07	*-0.08*	-0.47	*-0.09*	0.08	*-0.04*	-0.47	*-0.05*
4	0.22	*-0.08*	-0.23	*-0.09*	0.25	*-0.02*	-0.70	*-0.08*
7	1.73	*-0.04*	0.38	*-0.09*	1.37	*-0.01*	-0.41	*-0.06*
10	3.77	*0.03*	2.30	*-0.00*	3.12	*0.05*	0.76	*0.00*
14	4.93	*-0.06*	3.39	*-0.15*	4.73	*-0.02*	2.39	*-0.09*

[1] Populations reported as log CFU/g for average of triplicate samples for each treatment and sampling interval; standard deviation ≤0.30 log unless reported otherwise

[2] pH values reported on "as is" (unblended) samples for average of triplicate samples for each treatment and sampling interval; standard deviation ≤0.05 pH units unless reported otherwise.

K. Glass, Food Research Institute, UW-Madison
608.263.6935; kglass@wisc.edu

Table 6. Changes in populations of *Listeria monocytogenes* (log CFU/g[1]) and pH[2] in full-fat (FF) and reduced-fat (RF) cottage cheese with **0.15% Inhibitor D** (blended 0-time FF pH 5.20; RF pH 5.28) filled at 55°F and cooled to 45°F within 30 minutes (PMO cool) or within 72 hours (Industry Cool).

Days after fill	**Control FF PMO**		**0.15% Inhibitor D FF Industry**		**Control RF PMO**		**0.15% Inhibitor D RF Industry**	
	L. monocytogenes Log CFU/g	*pH*	*L. monocytogenes* Log CFU/g	*pH*	*L. monocytogenes* Log CFU/g	*pH*	*L. monocytogenes* Log CFU/g	*pH*
0	3.41	*5.32*	2.99	*5.22*	3.37	*5.34*	2.82	*5.35*
1	3.34	*5.29*	2.50	*5.24*	3.29	*5.32*	2.75	*5.32*
2	3.10	*5.25*	2.75	*5.14*	3.38	*5.35*	2.57	*5.36*
3	3.47±0.36	*5.24*	2.93	*5.23*	3.44	*5.29*	3.15	*5.33*
4	3.62	*5.24*	3.25	*5.23*	3.62	*5.31*	3.30	*5.38*
7	5.13	*5.28*	4.24	*5.24*	4.73±0.36	*5.33*	3.77	*5.32*
10	7.17	*5.35*	4.36	*5.30*	6.49	*5.39*	3.76±0.33	*5.40*
14	8.34	*5.26*	5.97	*5.26*	8.09	*5.32*	6.76	*5.31*
Change from 0-time								
1	-0.07	*-0.03*	-0.49	*0.02*	-0.08	*-0.01*	-0.08	*-0.03*
2	-0.31	*-0.07*	-0.24	*-0.08*	0.02	*0.01*	-0.26	*0.00*
3	0.07	*-0.08*	-0.06	*0.01*	0.08	*-0.04*	0.32	*-0.03*
4	0.22	*-0.08*	0.26	*0.01*	0.25	*-0.02*	0.47	*0.03*
7	1.73	*-0.04*	1.25	*0.02*	1.37	*-0.01*	0.94	*-0.03*
10	3.77	*0.03*	1.37	*0.09*	3.12	*0.05*	0.93	*0.04*
14	4.93	*-0.06*	2.98	*0.04*	4.73	*-0.02*	3.94	*-0.05*

[1] Populations reported as log CFU/g for average of triplicate samples for each treatment and sampling interval; standard deviation ≤0.30 log unless reported otherwise

[2] pH values reported on "as is" (unblended) samples for average of triplicate samples for each treatment and sampling interval; standard deviation ≤0.05 pH units unless reported otherwise.

K. Glass, Food Research Institute, UW-Madison
608.263.6935; kglass@wisc.edu

Table 7. Changes in populations of *Listeria monocytogenes* (log CFU/g[1]) and pH[2] in full-fat (FF) and reduced-fat (RF) cottage cheese with **0.1% Inhibitor E** (blended 0-time pH 5.25 FF; pH 5.28 RF) filled at 55°F and cooled to 45°F within 30 minutes (PMO cool) or within 72 hours (Industry Cool).

Days after fill	**Control FF PMO**		**0.1% Inhibitor E FF Industry**		**Control RF PMO**		**0.1% Inhibitor E RF Industry**	
	L. monocytogenes Log CFU/g	*pH*	*L. monocytogenes* Log CFU/g	*pH*	*L. monocytogenes* Log CFU/g	*pH*	*L. monocytogenes* Log CFU/g	*pH*
0	3.41	*5.32*	3.64	*5.32*	3.37	*5.34*	3.67	*5.40*
1	3.34	*5.29*	3.63	*5.25*	3.29	*5.32*	3.73	*5.32*
2	3.10	*5.25*	3.74	*5.25*	3.38	*5.35*	3.83	*5.31*
3	3.47±0.36	*5.24*	3.69	*5.25*	3.44	*5.29*	4.10	*5.32*
4	3.62	*5.24*	4.04	*5.25*	3.62	*5.31*	4.35	*5.31*
7	5.13	*5.28*	4.74	*5.28*	4.73±0.36	*5.33*	5.03	*5.38*
10	7.17	*5.35*	5.44	*5.26*	6.49	*5.39*	5.63	*5.26*
14	8.34	*5.26*	6.42	*5.16*	8.09	*5.32*	6.33	*5.17±0.08*
Change from 0-time								
1	-0.07	*-0.03*	-0.01	*-0.06*	-0.08	*-0.01*	0.07	*-0.08*
2	-0.31	*-0.07*	0.11	*-0.07*	0.02	*0.01*	0.17	*-0.08*
3	0.07	*-0.08*	0.06	*-0.06*	0.08	*-0.04*	0.43	*-0.07*
4	0.22	*-0.08*	0.41	*-0.06*	0.25	*-0.02*	0.68	*-0.09*
7	1.73	*-0.04*	1.10	*-0.04*	1.37	*-0.01*	1.36	*-0.01*
10	3.77	*0.03*	1.80	*-0.05*	3.12	*0.05*	1.96	*-0.13*
14	4.93	*-0.06*	2.79	*-0.15*	4.73	*-0.02*	2.67	*-0.22*

[1] Populations reported as log CFU/g for average of triplicate samples for each treatment and sampling interval; standard deviation ≤0.30 log unless reported otherwise

[2] pH values reported on "as is" (unblended) samples for average of triplicate samples for each treatment and sampling interval; standard deviation ≤0.05 pH units unless reported otherwise.

Table 8. Changes in populations of *Listeria monocytogenes* (log CFU/g[1]) and pH[2] in full-fat (FF) and reduced-fat (RF) cottage cheese with **0.1% Inhibitor E plus Live Culture** (blended 0-time pH 5.25 FF; pH 5.28 RF)) filled at 55°F and cooled to 45°F within 30 minutes (PMO cool) or within 72 hours (Industry Cool).

Days after fill	**Control FF PMO**		**0.1% Inhibitor E + Live Culture; FF Industry**		**Control RF PMO**		**0.1% Inhibitor E + Live Culture; RF Industry**	
	L. monocytogenes Log CFU/g	*pH*	*L. monocytogenes* Log CFU/g	*pH*	*L. monocytogenes* Log CFU/g	*pH*	*L. monocytogenes* Log CFU/g	*pH*
0	3.41	*5.32*	4.25	*5.30*	3.37	*5.34*	3.80	*5.39*
1	3.34	*5.29*	4.30	*5.26*	3.29	*5.32*	3.91	*5.31*
2	3.10	*5.25*	4.19	*5.24*	3.38	*5.35*	3.81	*5.27*
3	3.47±0.36	*5.24*	4.35	*5.21*	3.44	*5.29*	3.85	*5.28*
4	3.62	*5.24*	4.37	*5.24*	3.62	*5.31*	3.98	*5.31*
7	5.13	*5.28*	4.35	*5.24*	4.73±0.36	*5.33*	3.99	*5.35*
10	7.17	*5.35*	4.51	*5.23*	6.49	*5.39*	4.07	*5.30*
14	8.34	*5.26*	4.34	*5.17*	8.09	*5.32*	4.38	*5.26*
Change from 0-time								
1	-0.07	*-0.03*	0.05	*0.00*	-0.08	*-0.01*	0.12	*0.00*
2	-0.31	*-0.07*	-0.06	*-0.04*	0.02	*0.01*	0.01	*-0.07*
3	0.07	*-0.08*	0.10	*-0.06*	0.08	*-0.04*	0.06	*-0.12*
4	0.22	*-0.08*	0.12	*-0.09*	0.25	*-0.02*	0.19	*-0.11*
7	1.73	*-0.04*	0.10	*-0.06*	1.37	*-0.01*	0.19	*-0.07*
10	3.77	*0.03*	0.26	*-0.06*	3.12	*0.05*	0.27	*-0.04*
14	4.93	*-0.06*	0.09	*-0.08*	4.73	*-0.02*	0.58	*-0.09*

[1] Populations reported as log CFU/g for average of triplicate samples for each treatment and sampling interval; standard deviation ≤0.30 log unless reported otherwise

[2] pH values reported on "as is" (unblended) samples for average of triplicate samples for each treatment and sampling interval; standard deviation ≤0.05 pH units unless reported otherwise.

K. Glass, Food Research Institute, UW-Madison
608.263.6935; kglass@wisc.edu

Table 9. Changes in populations of *Listeria monocytogenes* (log CFU/g[1]) and pH[2] in full-fat (FF) and reduced-fat (RF) cottage cheese with **0.5% Inhibitor A** (blended 0-time FF pH 5.19; RF pH 5.24) filled at 55°F and cooled to 45°F within 30 minutes (PMO cool) or within 72 hours (Industry Cool).

Days after fill	Control FF PMO		0.5% Inhibitor A FF Industry		Control RF PMO		0.5% Inhibitor A RF Industry	
	L. monocytogenes Log CFU/g	*pH*	*L. monocytogenes* Log CFU/g	*pH*	*L. monocytogenes* Log CFU/g	*pH*	*L. monocytogenes* Log CFU/g	*pH*
0	3.41	*5.32*	3.20	*5.21*	3.37	*5.34*	3.39	*5.25*
1	3.34	*5.29*	3.24	*5.22*	3.29	*5.32*	3.25	*5.26*
2	3.10	*5.25*	3.28	*5.19*	3.38	*5.35*	3.28	*5.29*
3	3.47±0.36	*5.24*	3.08	*5.21*	3.44	*5.29*	3.24	*5.25*
4	3.62	*5.24*	3.19	*5.19*	3.62	*5.31*	3.25	*5.24*
7	5.13	*5.28*	3.14	*5.23*	4.73±0.36	*5.33*	3.21	*5.30*
10	7.17	*5.35*	3.11	*5.29*	6.49	*5.39*	2.96	*5.36*
14	8.34	*5.26*	3.07	*5.25*	8.09	*5.32*	3.04	*5.30*
Change from 0-time								
1	-0.07	*-0.03*	0.03	*0.02*	-0.08	*-0.01*	-0.14	*0.01*
2	-0.31	*-0.07*	0.08	*-0.02*	0.02	*0.01*	-0.11	*0.04*
3	0.07	*-0.08*	-0.12	*0.01*	0.08	*-0.04*	-0.15	*0.00*
4	0.22	*-0.08*	-0.02	*-0.01*	0.25	*-0.02*	-0.15	*-0.01*
7	1.73	*-0.04*	-0.06	*0.02*	1.37	*-0.01*	-0.18	*0.05*
10	3.77	*0.03*	-0.09	*0.09*	3.12	*0.05*	-0.43	*0.11*
14	4.93	*-0.06*	-0.13	*0.05*	4.73	*-0.02*	-0.35	*0.04*

[1] Populations reported as log CFU/g for average of triplicate samples for each treatment and sampling interval; standard deviation ≤0.30 log unless reported otherwise

[2] pH values reported on "as is" (unblended) samples for average of triplicate samples for each treatment and sampling interval; standard deviation ≤0.05 pH units unless reported otherwise.

K. Glass, Food Research Institute, UW-Madison
608.263.6935; kglass@wisc.edu

Table 10. Changes in populations of *Listeria monocytogenes* (log CFU/g[1]) and pH[2] in full-fat (FF) and reduced-fat (RF) cottage cheese with **0.3% Inhibitor A** (blended 0-time FF pH 5.20; RF pH 5.24) filled at 55°F and cooled to 45°F within 30 minutes (PMO cool) or within 72 hours (Industry Cool).

Days after fill	**Control FF PMO**		**0.3% Inhibitor A FF Industry**		**Control RF PMO**		**0.3% Inhibitor A RF Industry**	
	L. monocytogenes Log CFU/g	*pH*	*L. monocytogenes* Log CFU/g	*pH*	*L. monocytogenes* Log CFU/g	*pH*	*L. monocytogenes* Log CFU/g	*pH*
0	3.41	*5.32*	3.46	*5.26*	3.37	*5.34*	3.38	*5.31*
1	3.34	*5.29*	3.21	*5.23*	3.29	*5.32*	3.25	*5.28*
2	3.10	*5.25*	3.34	*5.25*	3.38	*5.35*	3.33	*5.29*
3	3.47±0.36	*5.24*	3.27	*5.22*	3.44	*5.29*	3.23	*5.28*
4	3.62	*5.24*	3.38	*5.17*	3.62	*5.31*	3.20	*5.24*
7	5.13	*5.28*	3.34	*5.25*	4.73±0.36	*5.33*	3.27	*5.31*
10	7.17	*5.35*	3.47	*5.29*	6.49	*5.39*	3.20	*5.37*
14	8.34	*5.26*	4.12	*5.25*	8.09	*5.32*	3.47	*5.30*
Change from 0-time								
1	-0.07	*-0.03*	-0.25	*-0.02*	-0.08	*-0.01*	-0.12	*-0.03*
2	-0.31	*-0.07*	-0.11	*0.00*	0.02	*0.01*	-0.05	*-0.02*
3	0.07	*-0.08*	-0.18	*-0.04*	0.08	*-0.04*	-0.14	*-0.04*
4	0.22	*-0.08*	-0.07	*-0.08*	0.25	*-0.02*	-0.17	*-0.07*
7	1.73	*-0.04*	-0.12	*0.00*	1.37	*-0.01*	-0.11	*0.00*
10	3.77	*0.03*	0.01	*0.03*	3.12	*0.05*	-0.17	*0.06*
14	4.93	*-0.06*	0.67	*0.02*	4.73	*-0.02*	0.09	*-0.01*

[1] Populations reported as log CFU/g for average of triplicate samples for each treatment and sampling interval; standard deviation ≤0.30 log unless reported otherwise

[2] pH values reported on "as is" (unblended) samples for average of triplicate samples for each treatment and sampling interval; standard deviation ≤0.05 pH units unless reported otherwise.

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	118
Committee:	

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

To amend the current requirement found in 16p (E) (1) (c) to quarterly mark the time accuracy of the recording thermometer on flow rate recording charts for use in continuous flow or aseptic processing equipment with magnetic flow meter based timing systems.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

The purpose of the recording thermometer-time accuracy test, as specified by *Appendix I Test #3* in the 2009 Pasteurized Milk Ordinance (PMO), is to record the time of pasteurization or aseptic processing. This information is captured on every pasteurizer's recording thermometer and is checked quarterly by regulatory testing. The purpose of a flow-rate recording thermometer is to measure and record the flow of milk through the system along with the status of the high and low-flow/loss of signal alarm. Duplicating the time accuracy test on the flow rate recording thermometer does not lend an extra layer of security since there is no standardization of time-scale divisions required or specified in the PMO for these types of flow-rate recording thermometers and this information is already being recorded on the recording chart.

Section 16p (E) (1) (c) identifies the information required to be found on flow rate recording charts for continuous-flow pasteurizers/aseptic processing equipment with magnetic flow meter based timing systems. As currently written in the 2009 PMO, this section requires all of the information identified for batch pasteurizers (Sub item a. 1-date; 2-number and location of recording thermometer; 3-product temperature; 4-exent of holding period; 5-airspace thermometer reading; 6-indicating thermometer reading; 7-quarterly time accuracy of recording thermometer; 8 amount & name of milk product; 9-record of unusual occurrences; 10-

signature/initials of operator; and 11-name of milk plant), save for items 3, 4, 5, and 6. In addition, it also requires a continuous record of the status of the high and low-flow/loss of signal alarms and a continuous record of the flow rate. By not exempting the quarterly time accuracy of the recording thermometers, item #7 found in sub-item a. of this section, the 2009 PMO requires the regulatory agency to perform Test #3 from Appendix I not only on the pasteurizer's recording chart, but also to repeat the test on the flow-rate recording chart as well.

This proposal respectfully requests that the Conference amend the current language in 16p (E) (1) (c) to exempt the requirement that the quarterly time accuracy for recording thermometers be duplicated on flow-rate recording charts for continuous flow pasteurizers or aseptic processing equipment with magnetic flow meter based timing systems.

C. Proposed Solution

Changes to be made on page(s): 103 of the (X - one of the following):

X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

Amend the 2009 PMO, page 103, Section 7, Standards for Grade "A" Milk and Milk Products, item 16p (E) (1) (c).

c. **Continuous-Flow Pasteurizers or Aseptic Processing Equipment with Magnetic Flow Meter Based Timing Systems:** Flow rate recording charts shall be capable of continuously recording flow at the flow alarm set point and at least 19 liters (5 gallons) per minute higher than the high flow alarm setting. Flow rate recording charts shall contain all the information specified in Subitem a. above, except (3), (4), (5), ~~and~~ (6), and (7), and in addition, shall include the following:
(1) A continuous record of the status of the high and low-flow/loss of signal alarms; and
(2) A continuous record of the flow rate.

Name: Chris Gordon, Environmental Health Manager

Agency/Organization: Virginia Department of Health

Address: 109 Governor Street, 5th Floor

City/State/Zip: Richmond, Virginia 23219

Telephone No.: (804) 864-7417 E-mail Address: christopher.gordon@vdh.virginia.gov

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	119
Committee:	

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

This proposal adds the slurry temperature requirements currently found in Appendix H into the Item 17p. Cooling of Milk and Milk Products section of the PMO.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

Slurry temperature requirements are currently buried in Appendix H and can be difficult to find when it is necessary to reference them. This proposal will place the same wording into the item 17p section where it can be easily referenced.

C. Proposed Solution

Changes to be made on page(s): p. 107 - 110 of the (X - one of the following):

X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

ITEM 17p. COOLING OF MILK AND MILK PRODUCTS

All raw milk and milk products shall be maintained at 7°C (45°F) or less until processed. All whey and whey products for condensing and/or drying shall be maintained at a temperature of 7°C

(45oF) or less; or 57°C (135°F) or greater until processed, except that acid-type whey with a titratable acidity of 0.40% or above, or a pH of 4.6 or below, is exempted from these temperature requirements.
If a slurry contains milk and/or milk products, tanks used to blend and hold such slurry shall be completely emptied and cleaned after each four (4) hours of operation or less, unless it shall be stored at a temperature of 7°C (45°F) or less, or at a temperature of 66°C (150°F) or more and be maintained thereat until the time of injection.
All pasteurized milk and milk products,.....

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. All raw milk and milk products shall.....
2. All whey and whey products.....
3. If a slurry contains milk and/or milk products, tanks used to blend and hold such slurry shall be completely emptied and cleaned after each four (4) hours of operation or less, unless it shall be stored at a temperature of 7°C (45°F) or less, or at a temperature of 66°C (150°F) or more and be maintained thereat until the time of injection.
~~3~~4. All pasteurized milk and milk products,.....
~~4~~5. All pasteurized milk and milk products,.....
~~5~~6. All pasteurized milk and milk products.....
~~6~~7. Each refrigerated room.....
~~7~~8. Each storage tank shall.....
~~8~~9. On delivery vehicles,.....
~~9~~10. All surface coolers.....
~~10~~11. Recirculated cooling water,.....
~~11~~12. Recirculated cooling water.....
~~12~~13. Water from an open,.....

Name: Robert Moore & Marian Ryan

Agency/Organization: FL Dept. of Agriculture, Division of Dairy Industry

Address: 3125 Conner Blvd, MS-C27

City/State/Zip: Tallahassee, FL 32399-1650

Telephone No.: (850) 487-1470 E-mail Address: Gary.newton@freshfromflorida.com

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	120
Committee:	Other Species

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

This Proposal makes corrections to the errors cited in Section 8-Animal Health of the PMO in relationship to what animal species are covered and not covered under the USDA Tuberculosis (TB) Eradication Program. It also reflects changes to the USDA Brucellosis Eradication Program under the Interim Rule to 9 CFR Part 78 and updates the references to obtain copies of the USDA TB and Brucellosis Eradication Programs cited in Appendix A. Animal Health Control of the PMO.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

FDA was notified by USDA after the electronic publication of the 2009 PMO that the references to the USDA Bovine Tuberculosis Eradication Program cited in Section 8-Animal Health of the PMO were inaccurate and in need of correction. The proposed wording is recommended by USDA to correct that inaccuracy.

An Interim Rule to 9 CFR Part 78 was published on December 27, 2010 making significant changes to the USDA Brucellosis Eradication Program. The proposed wording updates Section 8-Animal Health of the PMO to reflect those changes. The proposed wording is recommended by USDA to address these changes to their Program.

Also, USDA cited that the references for obtaining copies of the USDA Bovine Tuberculosis Eradication Program and the USDA Brucellosis Eradication Program needed to be updated and corrected. The proposed wording is recommended by USDA to update and correct those citations.

C. Proposed Solution

Changes to be made on page(s): 117, 118 and 129 of the (X - one of the following):

X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

~~Strike through~~ text to be deleted and underline text to be added.

*Make the following changes to the **2009 PMO**.*

Pages117-118:

SECTION 8. ANIMAL HEALTH

1. All milk for pasteurization shall be from herds ~~in Areas which have Modified Accredited Advanced Tuberculosis (TB) status or higher as determined by the USDA. Provided, that in an Area which fails to maintain such status, any herd shall have been accredited by said Department as tuberculosis free, or shall have passed an annual tuberculosis test, or the Area shall have established a tuberculosis testing protocol for livestock that assures tuberculosis protection and surveillance of the dairy industry within the Area and that is approved by FDA, USDA and the Regulatory Agency.~~ under a tuberculosis eradication program, which meets one (1) of the following conditions:

a. Areas which have Modified Accredited Advanced Tuberculosis (TB) status or higher as determined by the USDA; or

b. An Area which fails to maintain such status:

(1) Any herd shall have been accredited by USDA as tuberculosis free; or

(2) Shall have passed an annual tuberculosis test; or

(3) The Area shall have established a tuberculosis testing protocol for livestock that assures tuberculosis protection and surveillance of the dairy industry within the Area and that is approved by FDA, USDA and the Regulatory Agency.

NOTE: Under the Federal USDA Bovine TB Eradication Program, only cattle ~~and other hooved mammals (goat, sheep, water buffalo, etc.~~, bison, and captive cervids are covered within the USDA State TB status determination. Therefore, other hooved mammals (goats, sheep, water buffalo, etc.) are not covered within the program and shall comply with the option cited below.

Goat, sheep, water buffalo, or any other hooved mammal milk for pasteurization, ultra-pasteurization or aseptic processing, defined under this *Ordinance*, shall be from a herd or flock that is determined to be free of tuberculosis as provided by the development and implementation of a State administered tuberculosis-free herd certification program involving a documented surveillance program, which includes records supporting the tests required in this Section, and an official annual written certification from the State Veterinarian documenting their tuberculosis-free status. The surveillance program shall be documented and

the official annual written State tuberculosis-free certification shall be retained on file with the State Regulatory Agency. This official annual written State tuberculosis-free certification shall include a current list of Grade "A" non-cattle dairy herds and/or flocks (goats, sheep, water buffalo, etc.) that are covered within the documented surveillance program and contained within the official annual written State tuberculosis-free certification.

2. All milk for pasteurization shall be from herds under a brucellosis eradication program, which meets one (1) of the following conditions:

a. Located in a Certified Brucellosis-Free Area as defined by USDA and enrolled in the testing program for such areas; or

b. Meet USDA requirements for ~~an individually certified herd~~ a Certified Brucellosis-Free Herd; or

c. Participating in a milk ring testing program at least two (2) times per year at approximately one hundred eighty (180) day intervals and all herds with positive milk ring results shall have the entire herd blood tested within thirty (30) days from the date of the laboratory ring tests; or

d. Have an individual blood agglutination test on all cattle or bison six (6) months of age or older, except steers and spayed heifers, annually with an allowable maximum grace period not exceeding two (2) months.

NOTE: Under the Federal USDA Brucellosis Eradication Program…

Page 129 :

APPENDIX A. ANIMAL DISEASE CONTROL

Copies of the ~~*Uniform Methods and Rules; Bovine Tuberculosis Eradication, Uniform Methods and Rules for Establishment and Maintenance of Tuberculosis-Free Accredited Herds of Cattle, Modified Accredited Areas and Areas Accredited Free of Bovine Tuberculosis in the Domestic Bovine*~~ *Bovine Tuberculosis Eradication: Uniform Methods and Rules (available at http://www.aphis.usda.gov/animal_health/animal_diseases/tuberculosis/downloads/tb-umr.pdf),* and ~~recommended~~ *Brucellosis Eradication,: ~~Recommended~~ Uniform Methods and Rules, (available at http://www.aphis.usda.gov/animal_health/animal_diseases/brucellosis/downloads/umr_bovine_bruc.pdf),* current at the time of the adoption of this *Ordinance* are available electronically using the hyperlinks above or may be obtained from your State Veterinarian or:

Veterinary Services
Animal and Plant Health Inspection Service
U. S. Department of Agriculture
~~Federal Center Building~~
~~Hyattsville, MD 20782~~
4700 River Road, Unit 43
Riverdale, MD 20737
http://www.aphis.usda.gov/animal_health/

Or

Federal Area Veterinarian in Charge
VS, APHIS, USDA
Your State Capitol

It is recommended that Regulatory Agencies initiate and/or promote a mastitis control program. A well-planned and extended educational phase will encourage the support of producers and reduce the problems of enforcement. .....

Name:	CFSAN		
Agency/Organization:	Food and Drug Administration		
Address:	5100 Paint Branch Parkway		
City/State/Zip:	College Park, MD 20740		
Telephone No.:	(301) 436-2175	E-mail Address:	Robert.Hennes@fda.hhs.gov

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	121
Committee:	Scientific

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

Editorial clarification that Ultraviolet(UV) light disinfection of water as specified in Appendix D Section IV is equivalent to chemical disinfection for water reuse purposes.

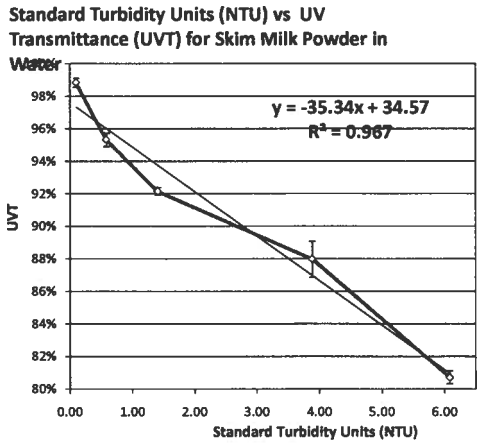
B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

Since the 2009 adoption of specific criteria for continuous disinfection of water by UV and for UV pasteurized equivalent water, inconsistencies have been discovered around how to bridge the specification of chemical disinfection of reuse water with providing a sustainable UV alternative.

Under some conditions, chlorine and other chemical disinfection of water in processing pipes can promote biofilms, accelerate pipe corrosion and encourage development of chemical resistance by pseudomonas, molds, spores, algae and other microbes.

On the other hand, UV disinfection can provide the same operational certainty and water quality as chemical disinfection when appropriate and designed and used correctly. UV disinfection can reduce biofilms, does not contribute to pipe corrosion and is particularly effective against chemical-resistant microbes, especially pseudomonas, when used in accordance with the criteria adopted in the 2009 PMO.

This proposal itemizes the editorial changes to specify appropriate UV disinfection as an alternative to chemical disinfection, with the same level of precautions, safety, monitoring and quality.



For example, to be eligible for reuse as Category I, water must not exceed a standard turbidity of 5 units (NTU). The analogous UV criterion that assures that the 5 NTU standard cannot be exceeded is the use of 85% UVT as the minimum for UV disinfection treatment. The graph above illustrates that water diluted with skim milk powder that exceeds the 5NTU standard will always have a lower UVT than 85% and water that has a UVT 85% or higher will always have a standard turbidity of less than 5 NTU.

C. Proposed Solution			
Changes to be made on page(s):		174-177	of the (X - one of the following):
x	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

Make the following changes to the 2009 Pasteurized Milk Ordinance. Appendix D V and VI

~~Strike-out~~ text to be deleted and <u>underlined</u> text to be added.

V. WATER RECLAIMED FROM MILK AND MILK PRODUCTS AND FROM HEAT EXCHANGERS OR COMPRESSORS IN MILK PLANTS

CATEGORY I. USED FOR POTABLE WATER PURPOSES

3. Water reclaimed from milk and milk products, a standard turbidity of less than five (5) units; or an electrical conductivity (EC) maintained in correlation with an organic content of less than 12 mg/L, as measured by the chemical oxygen demand or permanganate-consumed

test. When UV Disinfection per Appendix D is used, a UVT(Ultraviolet Transmittance) analyzer shall be utilized instead and set to a minimum UVT of 85%.
7. Approved chemicals, such as chlorine, with a suitable detention period, or UV Disinfection in accordance with the criteria in Appendix D may be used to suppress the development of bacterial growth and prevent the development of tastes and odors.
8. The addition of chemicals shall be by an automatic proportioning device, or, in the case of UV disinfection, an appropriate automatic dose calculation and display, prior to the water entering the storage vessel to assure satisfactory quality water in the storage vessel at all times.
9. When chemicals are added, a daily testing program for such added chemicals shall be in effect and such chemicals shall not add substances that will prove deleterious to the use of the water or contribute to product contamination. When UV disinfection is used, the automatic dose calculation and display shall be monitored daily.

CATEGORY II. USED FOR LIMITED PURPOSES

b. The water is treated with a suitable, approved chemical to suppress bacterial propagation by means of an automatic proportioning device, or by a UV disinfection device that complies with Appendix D that shall have an appropriate automatic dose calculation and display prior to the water entering the storage tank; or

VI. WATER RECLAIMED FROM HEAT EXCHANGER PROCESSES OR COMPRESSORS ON GRADE "A" DAIRY FARMS

8. Approved chemicals, such as chlorine, with a suitable retention period or UV disinfection that complies with the criteria in Appendix D may be used to suppress the development of bacterial growth and prevent the development of tastes and odors.
9. When chemicals are added, a monitoring program for such added chemicals shall be in effect and such chemicals shall not add substances that will prove deleterious to the use of the water or contribute to product contamination. When UV disinfection is used, a dose monitoring program shall be in effect.

Name:	Phyllis B. Posy		
Agency/Organization:	Atlantium Technologies		
Address:	11 HaMelacha Street		
City/State/Zip:	Beit Shemesh, Israel 99100		
Telephone No.:	718-770-7756	E-mail Address:	phyllisp@atlantium.com

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	122
Committee:	Tech

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

This proposal clarifies that the listed uses of Category II water (culinary steam, pre-rinsing, and CIP make-up) in the PMO are exclusionary and limiting, and adds to these approved applications the use of Category II water as a non-recirculated heat exchange media under specified conditions.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

There is no public health risk associated with allowing Category II reclaimed water to be used as a non-recirculated heat exchange media provided that when used to exchange heat with pasteurized milk and milk products, the plate or double/triple tube heat exchanger is designed and operated in accordance with 16p (D) Regenerative Heating.

C. Proposed Solution

Changes to be made on page(s): 176 of the (X - one of the following):

X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

CATEGORY II. USED FOR LIMITED PURPOSES

Reclaimed water may be used for the following limited purposes ~~including~~:

1. Production of culinary steam.
2. Pre-rinsing of the product surfaces where pre-rinses will not be used in milk or milk products.
3. Cleaning solution make-up water.
4. Non-recirculated heat exchange media.

Provided that for these uses, Items 3-11 of Category I are satisfied and shall be documented. Or, in the case of reclaimed water from heat exchangers or compressors, Items 5-11 are satisfied and shall be documented.

Name:	Dean Tjornehoj		
Agency/Organization:	California Dairies Inc.		
Address:	2000 North Plaza Drive		
City/State/Zip:	Visalia, California 93291		
Telephone No.:	(559)625-2200	E-mail Address:	dtjornehoj@californiadairies.com

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	123
Committee:	Tech

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

In Appendix H, the Pasteurized Milk Ordinance (PMO) describes how minor ingredients can be added to a High Temperature Short Time (HTST) pasteurization system. The currently listed method states that the slurry pump must be de-energized. De-energizing the pump has the effect of stopping all product flow within a loop, and does not allow a single pressurized loop to be used for multiple operations. This proposal is to allow an alternate mechanical method—use of Double-Block & Bleed valves that release to a drain—to prevent continued flow to the injection point. The proposal requires the Double-Block and Bleed valves to be tested to assure they fully isolate the system in conjunction with all events in which the FDD moves to diverted flow.

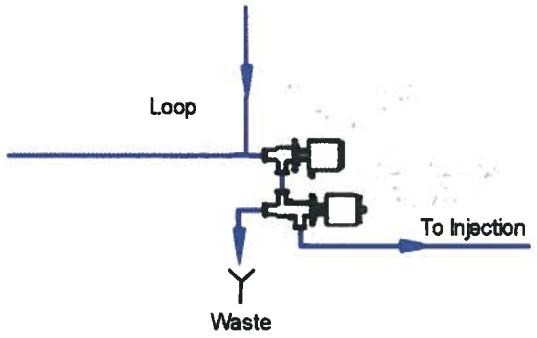
B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

Current requirements in the section "THE USE OF LIQUID INGREDIENT INJECTION WITHIN HTST SYSTEMS" (Appendix H) identify one method to prevent continued flow to the injection point: de-energizing the pump. Under this approach, a single pressurized loop cannot be used for multiple operations. This proposal would identify an additional, mechanical method to stop slurry delivery under required conditions while continuing slurry delivery to other systems using same pump.

To assure a safe, finished milk or milk product, HTST pasteurizers must maintain reliable time-temperature-pressure relationships whenever the system is in operation. The PMO includes redundant protections to ensure that raw milk does not come in contact with

pasteurized milk during processing. The proposal identifies an additional method for stopping raw product flow, ensuring that there is no pressure added to the raw side of the regenerator.

The proposed Double-Block & Bleed system is shown in the diagram below. The arrow to the right indicates the flow to the injection point; the arrow coming down and to the left is the loop of continued flow to additional processes.



C. Proposed Solution			
Changes to be made on page(s):	218	of the (X - one of the following):	
X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

Make the following changes to the 2009 Pasteurized Milk Ordinance.

~~Strike out~~ text to be deleted and underlined text to be added.

Appendix H. Pasteurization Equipment and Procedures and Other Equipment

THE USE OF LIQUID INGREDIENT INJECTION WITHIN HTST SYSTEMS

Milk or milk product flavoring slurries, condensed milk or milk products, and cream or skim for standardization and similar ingredients may be injected at a point after the last regenerator and before the timing pump, if all of the following conditions are met:

1. The slurry injection valve(s) is (are) closed and the slurry pump is de-energized:
   a. When the FDD is in inspect mode;

b. When the timing pump is not in operation; and
c. When the temperature is below the required pasteurization temperature and the FDD is not in the fully diverted position.

Note: In the case of a meter-based system, the slurry pump may remain energized provided the injection point has Double-Block and Bleed valves and will allow product under pressure to release to a drain. The valves shall be tested to assure they fully isolate the system in conjunction with all events in which the FDD moves to diverted flow.

2. The slurry injection valve(s) is (are) of the fail-safe type, spring-to-close and air-to-open, and are "block-and-bleed" design with a full port open to the atmosphere between the HTST isolation seat and the slurry pump when slurry is not being injected. . . .

Name: Debora Ruffie

Agency/Organization: Kraft Foods Global

Address: 801 Waukegan Road

City/State/Zip: Glenview, IL 60025

Telephone No.: 847-646-5163

E-mail Address: druffie@kraftfoods.com

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	124
Committee:	Tech

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

This Proposal provides a technical update, clarification and consolidation of the criteria for the use of magnetic flow meter based timing systems within HTST and HHST continuous flow pasteurization systems.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

This Proposal does not add any new technical requirements but is strictly a consolidation and clarification of current requirements and allowances provided in the PMO.

The proposed text includes the technical criteria that are already being utilized by FDA when they review and accept magnetic flow meters that are used as a component in these systems.

C. Proposed Solution

Changes to be made on page(s): 221 and 222 of the (X - one of the following):

X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

~~Strike through~~ text to be deleted and underline text to be added.

*Make the following changes to the **2009 PMO**.*

Pages 221-222:

MAGNETIC FLOW METER BASED TIMING SYSTEMS ~~FOR~~ WITHIN ~~HTST~~ CONTINUOUS FLOW ~~PASTEURIZERS~~ PASTEURIZATION SYSTEMS

Many ~~HTST~~ ~~pasteurizing system~~ pasteurization systems use magnetic flow meter based timing systems (MBTS). The flow through these timing systems is developed by a combination of flow promoting devices including booster and stuffer pumps, separators and clarifiers, homogenizers and positive displacement pumps.

Item 16p(B)2(f) of Section 7 provides for their use, provided they meet the following specifications for design, installation and use.

Components: Magnetic flow meter based timing systems shall consist of the following components:

1. A ~~sanitary~~ magnetic flow meter which has been reviewed by FDA or one (1) which ~~is equally accurate, reliable and will produce six (6) consecutive measurements of holding time within 0.5 seconds of each other~~ meets the following criteria for accuracy and reliability:

   a. Self-diagnostic circuitry that provides constant monitoring of all sensing, input and conditioning circuits. The diagnostic circuitry shall be capable of detecting "open" circuits, "short" circuits, poor connections and faulty components. Upon the detection of a failure of any component, the magnetic flow meter read-out shall blank or become unreadable.

   b. The electro-magnetic compatibility of the magnetic flow meter shall be documented and available to the Regulatory Agency. The magnetic flow meter shall be tested to determine the effects of electrostatic discharge, power fluctuation, conductive emission and susceptibility, and radiative emission and susceptibility.

   c. The effect of exposure to specific environmental conditions shall be documented. The magnetic flow meter shall be tested to determine the effects of low and high temperatures, thermal shock, humidity, physical shock and salt fog.

   d. The magnetic flow meter converter or transmitter and flow sensor, for those magnetic flow meters in which flow sensor sealing is required, shall be constructed so that they can be sealed by the Regulatory Agency.

   e. The calibration of the magnetic flow meter shall be protected against unauthorized changes.

   f. The magnetic flow meter shall be protected against unauthorized converter or transmitter replacement. If flow tubes are replaced, the Regulatory Agency shall be notified and such replacement shall be regarded as a replacement of the magnetic flow meter and subject to Regulatory Agency inspection and all applicable tests under Appendix I. of this *Ordinance*.

   g. The flow tube shall be encased in appropriate material and constructed in such a manner that the final assembly complies with the conditions cited within Item 11p of this *Ordinance*.

Calibration: The calibration shall be based on multiple points for the entire range of the magnetic flow meter for MBTS application. The magnetic flow meter shall be tested against a traceable NIST standard. The procedure(s) used for the magnetic flow meter calibration is documented and available to the Regulatory Agency.

Accuracy: At mid range, six (6) consecutive flow measurements are taken at the same flow setting. From these six (6) measurements, the standard deviation is calculated. The standard deviation for these measurements shall be less than 0.5%. Compliance of the magnetic flow meter would be determined through the actual installation field-testing of the magnetic flow meter.

2. Suitable converters for conversion of electric and/or air signals to the proper mode for the operation of the system.

3. A suitable flow recorder capable of recording flow at the flow alarm set point and also at least 19 liters (5 gallons) per minute higher than the flow alarm setting. The flow recorder shall have an event pen that shall indicate the status of the flow alarm with respect to flow rate.

4. A flow alarm, with an adjustable set point, shall be installed within the system which will automatically cause the FDD to be moved to the divert position whenever excessive flow rate causes the milk or milk product holding time to be less than the legal holding time for the pasteurization process being used. The flow alarm shall be tested by the Regulatory Agency in accordance with the procedures of Appendix I, Test 11, 2.A and B at the frequency specified. The flow alarm adjustment shall be sealed. **NOTE:** Test 11, 2.A is not applicable to HHST systems.

5. A low-flow or loss-of-signal alarm shall be installed with the system, which will automatically cause the FDD to be moved to the divert position whenever there is a low-flow or loss-of-signal from the magnetic flow meter. The low-flow or loss-of-signal provision shall be tested by the Regulatory Agency in accordance with Appendix I, Test 11, 2.C at the frequency specified. The low-flow or loss-of-signal provision shall be sealed.

6. For HTST systems, ~~When~~ when the legal flow rate has been reestablished, following an excessive flow rate, a time delay ~~must~~ shall be instituted, which will prevent the FDD from assuming the forward-flow position ~~until~~ for at least a minimum of fifteen (15) ~~seconds, for milk or milk product,~~ or twenty-five (25) seconds ~~for eggnog and similar products, of continuous legal flow has been re-established~~ depending upon the product being pasteurized and the temperature being utilized. The time delay ~~must~~ shall be tested and sealed by the Regulatory Agency ~~and if it is of the adjustable type shall be sealed~~.

For HHST systems, when the legal flow rate has been reestablished, following an excessive flow rate, a time delay at least as long as the legal flow rate shall be instituted, which will prevent the FDD from assuming the forward-flow position until at least the legal holding time within the holding tube has been reestablished. This time delay shall be built into the sequence logic that requires all conditions for legal pasteurization to be satisfied and that legal pasteurization temperature exists from the holding tube to the FDD, before the FDD can assume the forward-flow position.

7. For HTST systems, ~~A~~ a sanitary check valve or normally closed automatically controlled sanitary valve shall be installed with the magnetic flow meter to prevent a positive pressure in the raw milk or milk product side of the regenerator whenever a power failure, shutdown or flow-diversion occurs. **NOTE:** This provision is not applicable to HHST systems.

8. For HTST systems, ~~When~~ when a regenerator is used with large systems, it will be necessary to bypass the regenerator during start-up and when the FDD is in the diverted-flow position. Care ~~should~~ shall be taken in the design of such bypass systems to assure that a dead-end does not exist. A dead-end could allow milk or milk product to remain at ambient temperature for long periods of time and allow bacterial growth in the milk or milk product.

Caution ~~should~~ shall also be observed with such bypass systems and any valves used in them so that raw milk or milk product will not be trapped, under pressure in the raw regenerator plates, and not have free drainage back to the constant-level tank when shutdown occurs. **NOTE:** This provision is not applicable to HHST systems.

9. ~~Most systems will utilize a dual stem FDD and will be using the timing pump during the CIP cleaning cycle. All public health controls, required of such systems, must be applicable.~~ When switching to the "CIP" position, the FDD ~~must~~ shall move to the divert position and ~~must~~ shall remain in the diverted-flow position for at least ten (10) minutes, regardless of temperature, and for HTST systems the booster pump cannot run during this ten (10) minute time delay.

10. All MBTS pasteurization systems shall be designed, installed and operated so that all applicable tests required by Section 7, Item 16p(E) can be performed by the Regulatory Agency, at the frequency specified. (Refer to Appendix I.) Where adjustment or changes can be made to these devices or controls, appropriate seals shall be applied by the Regulatory Agency after testing, so that changes cannot be made without detection.

11. Except for those requirements directly related to the physical presence of the timing pump, all other requirements of the most recent edition of this *Ordinance* are applicable.

Placement of Components: Individual components in ~~the~~ a magnetic flow ~~meter based timing systems~~ MBTS shall comply with the following placement conditions:

1. The timing ~~pump~~ system's flow promoting device(s) shall be located ~~downstream~~ upstream from the ~~raw milk or milk product regenerator section, if a regenerator is used~~ magnetic flow meter.

2. The magnetic flow meter shall be placed ~~before the holding tube and~~ after ~~any bypassed regenerator(s)~~ the last raw product regenerator outlet and upstream of the holding tube ~~any bypassed regenerator(s)~~. There shall be no intervening flow-promoting components between the magnetic flow meter and the holding tube.

3. For HTST systems, ~~The~~ when a ~~control valve~~ sanitary check valve or normally closed automatically controlled sanitary valve, as described in #7 above, is used with ~~the~~ a variable or constant speed flow promoting device, ~~may~~ it shall be located downstream ~~of the magnetic flow meter~~ of the last regenerator outlet and upstream of the holding tube. **NOTE:** This provision is not applicable to HHST systems.

~~4. The magnetic flow meter, the sanitary check valve or normally closed control valve, shall all be located upstream from the start of the holding tube.~~

~~5~~ 4. All flow-promoting devices, which are upstream of the FDD~~, such as booster and stuffer pumps, separators and clarifiers, homogenizers and positive displacement pumps~~ and which are capable of generating flow through the FDD, shall be properly interwired with the FDD so that they may run and produce flow through the system at sub-legal temperatures, only when the FDD is in the fully diverted position and ~~when~~ in "Product" run mode, or "CIP" mode after the ten (10) minute time delay has timed out. Such flow promoting devices shall be de-energized in "Inspect" mode. Separators or clarifiers that continue to run, after they are de-energized ~~must~~ shall be automatically valved-out of the system, with fail-safe valves, so that they are incapable of producing flow.

~~6~~ 5. There shall be no product entering or leaving the system, i.e., cream or skim milk from a separator or other product components, between the magnetic flow meter and the ~~FDD~~ holding tube.

~~7~~ 6. The magnetic flow meter shall be so installed that the milk or milk product has contact with both electrodes at all times when there is flow through the system. This is most easily

accomplished by mounting the flow tube of the magnetic flow meter in a vertical position with the direction of flow from the bottom to the top. However, horizontal mounting is acceptable when other precautions are taken to assure that both electrodes are in contact with the product and the horizontal line shall remain full of liquid during operation. ~~They should~~ Magnetic flow meters shall not be mounted on a ~~high~~ horizontal line that may be only partially full and thereby trap air.

~~8~~ 7. The magnetic flow meter shall be piped in such a manner that at least ten (10) pipe diameters of straight pipe exists, upstream and downstream from the center of the magnetic flow meter, before any elbow or change of direction takes place. Except that other piping configurations upstream and downstream of the magnetic flow meter may also be used if they have been reviewed and found acceptable to FDA and the Regulatory Agency.

Name:	CFSAN		
Agency/Organization:	Food and Drug Administration		
Address:	5100 Paint Branch Parkway		
City/State/Zip:	College Park, MD 20740		
Telephone No.:	(301) 436-2175	E-mail Address:	Robert.Hennes@fda.hhs.gov

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	125
Committee:	

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

This Proposal addresses a change to Appendix H-Pasteurization Equipment and Procedures and Other Equipment, V-Criteria for the Evaluation of Electronic Data Collection, Storage and Reporting of the PMO to ensure that the milk plant has a person available to assist the regulatory/rating and FDA person with obtaining and reviewing electronic records when an inspection/rating is being conducted.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

Appendix H, V-Criteria for the Evaluation of Electronic Data Collection, Storage and Reporting of the PMO specifies that when electronic records replace manual records a person must be assigned and identified as responsible for the system.

Further clarity is needed to assure that the assigned and responsible person, or someone familiar with the electronic record system, is present in the facility when there is an inspection/rating, or can be present within some reasonable period of time. This is so the inspector/rating or FDA official doesn't have to attempt to access the reports themselves without or with limited assistance. A milk plant person familiar with the system being present will also make the inspector/rating official more confident that the electronic reporting system is being properly maintained, used, and in compliance with this Section of the PMO.

This additional guidance will help the milk plant also. It will ensure that they have staff and policies in place that protect their interests during inspections/ratings and record reviews.

C. Proposed Solution			
Changes to be made on page(s):	251	of the (X - one of the following):	
X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

*Make the following changes to the **2009 PMO**.*

~~Strike through~~ text to be deleted and underline text to be added.

APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT

V. CRITERIA FOR THE EVALUATION OF ELECTRONIC DATA COLLECTION, STORAGE, AND REPORTING

CRITERIA

The following criteria are to be used for the evaluation of electronic collection, storage and recording or reporting of any information required within Items 12p and 16p(E). of Section 7 of this *Ordinance*.

NOTE: These criteria do not address computer instrumentation or the electronic control of pasteurization for public health safety.

All computer-generated records and reports shall contain the information required in this *Ordinance* that is applicable. The computerized data collection, storage, and reporting system must have an assigned and identified representative from the milk plant that is responsible for the system. This person's name must be available to the Regulatory Agency and FDA. This person, or a person familiar with the reporting interface of the computerized data collection, storage and reporting system, shall be available to the Regulatory/Rating Agency and FDA at the time that the records are inspected and reviewed.

Name: Mike Wiggs

Agency/Organization: Idaho Department of Agriculture

Address: PO Box 790

City/State/Zip: Boise, Idaho 83701

Telephone No.: 208-736-3077 E-mail Address: mike.wiggs@agri.idaho.gov

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	126
Committee:	

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

This Proposal addresses a change to Appendix H-Pasteurization Equipment and Procedures and Other Equipment, V-Criteria for the Evaluation of Electronic Data Collection, Storage and Reporting of the PMO to clarify a potential misinterpretations that additional operator's signatures are required for raw and heat-treated milk and milk product storage tank's temperature records when using electronic records compared to the operator's signatures required for manual records as addressed in the PMO.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

Appendix H, V, Criteria for the Evaluation of Electronic Data Collection, Storage and Reporting was added to the PMO at the 2007 NCIMS Conference. Since then, during FDA and State training courses, individuals have often asked about the signature requirement cited in Item 8 of the Criteria section. The last sentence in Item 8 states: "A login must occur whenever an operator changes and at a minimum frequency of once every twenty-four (24) hours." The way this is worded, it would appear that raw and heat-treated milk and milk product storage tank's temperature records would need to indicate logins every 24 hours, which would require a modification to nearly all existing systems in milk plants today, including both manual and electronic records. These raw and heat-treated milk and milk product storage tank's temperature records typically cover a longer period of time, such as seven (7) day.

The intent of the original wording that was passed in 2007 was that this sentence only applied to pasteurization records. It was written to cover the rare case of when a pasteurizer might run over twenty four (24) hours with only one (1) operator and without any events occurring.

With this scenario, it would require a login every twenty four (24) hours.

Also, the third paragraph under the CRITERIA section states: "All computer-generated records and reports shall contain the information required in this *Ordinance* that is applicable." This covers any electronic requirements for non-pasteurization system records.

This Proposal simply edits this sentence to clarify the original intent for inspectors, milk plants including farms, and to limit the twenty four hour login requirement only to pasteurization records.

C. Proposed Solution

Changes to be made on page(s): 252 of the (X - one of the following):

X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

*Make the following changes to the **2009 PMO**.*

~~Strike through~~ text to be deleted and underline text to be added.

APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT

V. CRITERIA FOR THE EVALUATION OF ELECTRONIC DATA COLLECTION, STORAGE AND REPORTING

CRITERIA

Page 252

8. The electronic computerized data collection, storage, and reporting system shall provide for any signatures or initials required by this *Ordinance*. Acceptable operator signatures or initials, captured electronically, may be any combination of alpha and/or numeric characters that identify the individual performing the test or operation. Input of this signature or initials may be done by any means, including, but not limited to, a biometric reader, a card or radio frequency device, or by simple direct entry that provides a unique identifier directly associated with a specific person. Input of this signature or initials must occur each time it is required by this *Ordinance*. ~~A~~ In the case of pasteurization and aseptic processing records, a login must occur whenever an operator changes and at a minimum frequency of once every twenty-four (24) hours.

Name:	Mike Wiggs
Agency/Organization:	Idaho Department of Agriculture
Address:	PO Box 790
City/State/Zip:	Boise, Idaho 83701
Telephone No.:	208-736-3077
E-mail Address:	Mike.wiggs@agri.idaho.gov

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	127
Committee:	Tech

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

This Proposal addresses a change to Appendix H-Pasteurization Equipment and Procedures and Other Equipment, VI, Criteria for the Evaluation of Computerized Systems for Grade "A" Public Health Controls to include new frequency drive technology in the sealing process of a pasteurization system; thereby, timing pump speed cannot be controlled through a network or web interface.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

Appendix H, VI, Criteria for the Evaluation of Computerized Systems for Grade "A" Public Health Controls requires that the public health safety devices are sealed; thereby, changes cannot be made. With new frequency drive pump speed control technology it may provide a means for the sealing of this frequency drive controller to be missed.

This technology network motor controls including frequency drives (motor speed and stop/start control) to be accomplished through a network interface, and often accessible through the internet. At times the Regulatory Agency will seal the keypad of the motor frequency drive, but a speed change can still be performed remotely. Mostly, this happens as an oversight in the project design. This interface needs to be disconnected and the device needs to be hardwired.

This Proposal adds language to the PMO to bring this to the attention of designers, milk plants, and regulatory officials.

C. Proposed Solution			
Changes to be made on page(s):	256	of the (X - one of the following):	
X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

*Make the following changes to the **2009 PMO**.*

~~Strike through~~ text to be deleted and underline text to be added.

APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT

VI. CRITERIA FOR THE EVALUATION OF COMPUTERIZED SYSTEMS FOR GRADE "A" PUBLIC HEALTH CONTROLS

CRITERIA

Page 256

4. The status of the inputs and outputs of the public health computer may be provided as inputs only to other computer systems and all public health outputs or devices shall be controlled by direct hard-wiring from the output terminal bus of the computer to the device. This includes solenoids, motor speed controls, such as frequency drives, and motors located within the HTST or HHST system. The wiring connections must be provided with isolation protection such as relays, diodes, or optical-coupling devices to prevent the public health outputs from being driven by the other computer system. Digital outputs from another computer may be connected to an input of the public health computer in order to request the operation of a device controlled by the public health computer.

Name: Mike Wiggs

Agency/Organization: Idaho Department of Agriculture

Address: PO Box 790

City/State/Zip: Boise, Idaho 83701

Telephone No.: 208-736-3077 E-mail Address: mike.wiggs@agri.idaho.gov

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	128
Committee:	Tech

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

This Proposal addresses a change to Appendix H-Pasteurization Equipment and Procedures and Other Equipment, VI, Criteria for the Evaluation of Computerized Systems for Grade "A" Public Health Controls to eliminate a second memory chip that was preferable in older pasteurization system's computer/programmable logic controller technology; however, now has detrimental potential with newer technology.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

Appendix H, VI, Criteria for the Evaluation of Computerized Systems for Grade "A" Public Health Controls has given designers and builders of these pasteurization control system's systems the concept that a second memory chip needs to be added for the computer to comply with the PMO requirements. This was useful for technology available 10-15 years ago, since a power failure could cause program loss and require a complete inspection and evaluation.

A second memory chip, in today's common technology, is never used in practical application. This is because permanent memory is always included in every brand of milk plant floor computer. When a second memory chip is added, is saves a separate copy of the operating program that is not used nor accessed until a power failure is realized. Then, the older program in this chip will overwrite the memory of the active memory, thereby erasing all changes that have been made to protect public safety over the past days/months/years without any warning or notice.

This has been brought to the attention of the Regulatory Agency several times in the recent past as an inspector noticing that a pasteurizer has "reverted to an older version of ladder

logic" by itself. This is typically discovered during a routine inspection, and is often unknown how long the program has been functioning on the older version. It would seem the obvious answer would be to make sure the program is always copied from the active memory to the secondary memory chip, but there is no external indication this chip is present. As the integrator or milk plant engineers do change over the years, the history of this chip being present is forgotten.

Appendix H, VI, Criteria for the Evaluation of Computerized Systems for Grade "A" Public Health Controls, CRITERIA, Item 8 states: "The computer program used to control the required public health functions of HTST or HHST pasteurizers must be stored in some form of read-only memory (ROM) and be available when the public health computer is turned on." This statement can remain as is, because all computers/programmable logic controllers manufactured in the last fifteen (15) years have both RAM and ROM as standard functions, without exception. They also automatically copy and store the program in both, exactly as the PMO would require.

Appendix H, VI, Criteria for the Evaluation of Computerized Systems for Grade "A" Public Health Controls, CRITERIA, Item 17; however, further makes statements about RAM and ROM being two (2) different memory choices. This is what confuses integrators and engineers into installing a second memory chip (second ROM) and creating hidden storage of old memory that corrupts the changes to the public health system.

Two (2) solutions can accomplish the correction of this detrimental potential effect. First, this Proposal changes the language in Appendix H to remove the indication that new systems being built should have this second chip installed. Second, this Proposal changes the language in Appendix H to recommend the presence of a second memory chip only if the public health computer is an old version pre-dating built in RAM and ROM.

C. Proposed Solution

Changes to be made on page(s): 258 of the (X - one of the following):

X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

*Make the following changes to the **2009 PMO**.*

~~Strike through~~ text to be deleted and <u>underline</u> text to be added.

APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT

VI. CRITERIA FOR THE EVALUATION OF COMPUTERIZED SYSTEMS FOR GRADE "A" PUBLIC HEALTH CONTROLS

17. Computers require high quality; clean, well-regulated power supplies to operate reliably and safely. Spurious voltage spikes can cause unwanted changes in public health computer RAM. To assure the public health computer will execute its functions error free the following items parameters must be considered:

a. A "clean" power source that is relatively free of spikes, interference and other irregularities shall be supplied to the public health computer.

b. The correct program should be confirmed at the time of sealing. (Refer to the criteria cited within #9 of this Section).

c. The output bus "last state" switch should be in the "off" or "fail-safe" position which will stop all functions of the HTST or HHST pasteurizer in case of a spurious program error.

d. All public health computer outputs shall not have any operator override switches and must be wired in a manner that only allows the public health PLC complete control.

~~Some mechanical and electrical components also deteriorate with age. One (1) solution is to have two (2) permanent programs in the public health computer; one (1) in RAM and one (1) in ROM. Through a self-diagnostic test, these two (2) programs could be compared routinely. If there were differences in the programs, the public health computer would go into default mode. Another solution would be to download the program from ROM to RAM at every start-up. A third solution could be to have the public health computer read the program directly from unchangeable ROM. However, this approach is practical only in large volume (home appliances, etc.) applications. For most small volume applications, the ROM's are field alterable, such as EPROMS, EEPROMS and EAPROMS. These types of computer programs cannot be relied upon to maintain a permanent record.~~

e. Public health computers shall have built in RAM and ROM, as is the case in most PLC's. If the computer predates built in ROM, it must have ROM memory added, and be configured to download the program from ROM to RAM at every start-up. (Note: becomes effective five (5) years from the date that IMS-a-48 becomes effective)

It is necessary that the installer or designer for the public health PLC ensure that the proper program is in the public health computer memory before the Regulatory Agency seals the computer.

Name: Mike Wiggs

Agency/Organization: Idaho Department of Agriculture

Address: PO Box 790

City/State/Zip: Boise, Idaho 83701

Telephone No.: 208-736-3077 E-mail Address: mike.wiggs@agri.idaho.gov

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	129
Committee:	HACCP

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

To correct a typographical error on the Milk and Milk Product Continuous-Flow (HTST and HHST) Pasteurization --- CCP Model HACCP Plan Summary.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

Correct a typographical error and clarify the intent of the model.

C. Proposed Solution

Changes to be made on page(s): 267 of the (X - one of the following):

X	2009 PMO		2009 EML
	2009 MMSR		2400 Forms
	2009 Procedures		2009 Constitution and Bylaws

Modify the 2009 PMO, page 267
Milk and Milk Product Continuous-Flow (HTST and HHST) Pasteurization --- CCP Model HACCP Plan Summary.

Modify the footnote at the bottom of the model table on page 267 of the 2009 PMO to read as below:

**Every particle of milk or milk product is heated, in a properly designed, calibrated and operated pasteurizer, to one of the temperature and time combinations specified in the current *Grade "A" PMO*.

Name:	Jason Crafts, Chair		
Agency/Organization:	NCIMS HACCP Implementation Committee		
Address:	1105 North 1000 West		
City/State/Zip:	Logan, Utah 84321		
Telephone No.:	435 713 6158	Telephone No.:	435 713 6158

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	130
Committee:	SSCC

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			
FINAL ACTION			

A. Summary of Proposal

Establish a NCIMS Single Service Certification Pilot Committee (SSCPC) to set-up a 2-year pilot program to certify private parties that would be qualified to conduct the routine inspection and listing activities of NCIMS single service facilities. Such a pilot would start with a few volunteering states and listed single service facilities within those states in order to develop a solid check & balance system and report back to the 2013 Conference.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

The NCIMS Single Service Program has evolved from a program where recognized private parties as well as state regulatory employees conducted inspections and listings of single service facilities in the US and foreign countries. Presently, all US-based single service facilities providing primary packaging for Grade "A" milk products are inspected and listed by state dairy inspectors and listing officers, respectively. Foreign single service plants are inspected and listed by private parties whose qualifications meet FDA's unofficial requirements.

State dairy programs are facing significant financial and staffing pressure and many are making deep cuts to their dairy regulatory programs. One area that may provide some relief for these programs without jeopardizing the NCIMS commitment to safe Grade "A" products, is to try expanding the use of private parties recognized by FDA to inspect and list US-based single service companies. Currently there are approximately 450 listed US and 160 listed foreign single service plants. The system of using private parties meeting informal qualifications established by FDA has been successfully working for over 25% of the total number of NCIMS single service listings.
Such a private-based system, with the correct internal procedures, criteria and checks and

balances built by an NCIMS Single Service Certification Pilot Committee whose membership includes state regulatory, state rating, FDA, dairy processors and single service representatives should provide significant resource relief for most state dairy regulatory programs. Estimating that each US single service plant takes approximately 8 hours of time to inspect/list, complete the paperwork and handle phone calls and other activities related to this process, states together could save 3600 hours of time (450 days per year), which could be re-directed toward ensuring compliance with Grade "A" dairy farms and plants. This is a substantial savings that if developed correctly, would leverage decreasing state resources so their programs can focus where they have the most impact, dairy farms and dairy plants.

C. Proposed Solution

Changes to be made on page(s): _____ of the (X - one of the following):

_____ 2009 PMO _____ 2009 EML

_____ 2009 MMSR _____ 2400 Forms

_____ 2009 Procedures _____ 2009 Constitution and Bylaws

Establish a NCIMS Single Service Certification Pilot Committee (SSCPC) for the purpose of establishing and implementing a pilot program to develop criteria that will be used to evaluate and certify non-regulatory private parties to conduct the routine inspection and listing activities for US single service facilities. Once this criteria has been developed, to solicit private parties to submit information that will be used by the SSCPC to identify acceptable private parties to conduct routine NCIMS inspections and listings of single service facilities in states that agree to participate in the pilot. The SSCPC shall also establish a monitoring system to evaluate the effectiveness of the pilot program.

It is recognized that sections of the Procedures that designate only state rating officers (SROs) as qualified to conduct listings of NCIMS single service plants will be temporarily suspended only for those states and US single service plants participating in this pilot.

The SSCPC shall begin its work immediately after adoption of this proposal by the 2011 NCIMS Conference, appointment of a Chair by the NCIMS Executive Board and acceptance of a list of SSCPC members by the NCIMS Executive Board. The SSCPC shall periodically report to the NCIMS Executive Board on their progress and provide an update report to the 2013 Conference.

The NCIMS Single Service Certification Pilot Committee's responsibilities shall end on December 31, 2013, unless renewed by the 2013 NCIMS Conference.

Name:	Allen Sayler & Ken Anderson		
Agency/Organization:	Randolph Associate Inc. & Harold Wainess & Associates		
Address:	3820 3rd Ave S, Suite 100 & 3335-E North Arlington Heights Road		
City/State/Zip:	Birmingham, AL 35222 & Arlington Heights, IL 60004		
Telephone No.:	202-841-1029 & (847) 259-6400	E-mail Address:	Allen.sayler@raiconsult.com & Kenderson@aol.com